



July 12, 2005

Mark B. McClellan, MD, PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

Attn: CMS-1282-P

Re: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing

Facilities for FY 2006, Proposed Rule, 70 FR 29070, May 19, 2005, CMS-1282-P

Dear Dr. McClellan:

The American Association of Homes and Services for the Aging (AAHSA) is pleased to submit the attached comments on *Medicare Program: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006, Proposed Rule, 70 FR 29070, May 19, 2005, CMS-1282-P.*

These comments were developed by Dr. Barbara Manard, based on an extensive review of the methodology CMS is using to recalibrate the RUGS. AAHSA also had feedback on the proposed rule from hundreds of our members. As Dr. Manard's comments reflect, much work has been done by the CMS staff. Much work remains!

This proposal has enormous implications for Medicare beneficiaries and those who serve them. AAHSA will continue to assist CMS to achieve the goals of the proposed rule to recognize needed levels of care and provide incentives to ensure the care is appropriately delivered. To this end, we urge you to issue the next version of the document as an Interim Final Rule, so that the work may continue before a final rule is put in place, in light of all the complexities that have surfaced during this process.

We thank you and your staff for being open to our comments and suggestions. We have great respect for your leadership and hard work.

Many

Sincerely,

William L. Minnix, Jr. President and CEO



July 12, 2005

Dr. Mark B. McClellan Administrator Centers for Medicare and Medicaid Services Hubert Humphrey Building, Room 445-G 200 Independence Avenue, SW Washington, DC 20201

Attention: CMS-1282-P

RE: CMS-1282-P: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006

Dear Dr. McClellan:

The American Association of Homes and Services for the Aging (AAHSA) appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid (CMS) Proposed Rule: Medicare Program; Prospective Payment system and consolidated billing for Skilled Nursing facilities for FY 2006, published in the Federal Register on May 19 2005.

The members of AAHSA (<u>www.aahsa.org</u>) serve two million people every day through mission-driven, not-for-profit organizations dedicated to providing the services people need, when they need them, in the place they call home. Our members offer the continuum of aging services: assisted living residences, continuing care retirement communities, nursing homes, home and community-based services, outreach programs, and senior housing. AAHSA's commitment is to create the future of aging services through quality the public can trust.

BACKGROUND

The Balanced Budget Act of 1997 (BBA) required CMS to develop a perspective payment system for skilled nursing facilities and to publish updated rates and the casemix classification to be used before August 1 for rates in effect October 1 of the same year. For cost reporting periods on or after July 1, 1998, CMS implemented a SNF PPS that reimburses a prospective rate, which is based on the Resource Utilization Groups version three (RUG-III) classification system, to SNFs for services provided to residents covered by Medicare Part A. The prospective rate covers not only the nursing and

Dr. Mark B. McClellan Page 2 July 12, 2005

therapy services normally provided under Medicare Part A, but also consolidates nearly all Medicare Part B services, with some exceptions, that are provided to a SNF resident.

Immediately after the rule implementing the SNF PPS was published on May 12, 1998, clinicians, researchers, and provider groups began pointing out a serious problem with the new system: it failed to account for differences among patients in the use of non-therapy ancillaries (NTA). These are primarily medications, but also include supplies, laboratory tests, and respiratory therapy. The new system assumes that NTA costs are correlated with nursing time and hence uses the nursing index part of the RUGs system to account for differences among patients with respect to NTA. Clinicians and provider groups supplied CMS and Congress case after case example of how the new system failed to account properly for NTA costs. The problem was identified as being especially acute among medically complex patients, who generally require the most costly NTA.

Congress took note. For example, in September 1999 the Appropriations Committee Report for the Department of Health and Human Services stated, "The Committee has heard concerns regarding the equity of the new Medicare SNF prospective payment system as it relates to non-therapy ancillaries. The demonstration upon which the new system was based did not include this class of items and services [in the prospective rate; they were treated as a pass-through]." The Committee urged CMS to fix the problem.

In response to these concerns, and acknowledging problems with the rule, CMS contracted with Abt Associates for research on the issue. The initial findings from that study, released October 1, 1998, confirmed that RUG III has little ability to predict the use of NTA and that the new PPS contained financial disincentives to care for certain medically complex patients with high NTA costs.²

Various members of Congress stepped up calls for an immediate temporary solution as well as longer-range solutions. For example, Senator Orrin Hatch (R-Utah) said in the Senate, "Unless relief is provided and this anomaly in the payment system is corrected, a major impediment will remain for certain patients with high non-therapy ancillary costs to receive Medicare services in nursing facilities. An immediate transitional modification is needed before irreparable harm is done to quality care and access for high cost patients....We must ... develop longer term solutions for these crucial services, but first we must do no harm in the interim." Senator Hatch expressed concern that without amendment the new system would drive some providers to sub

¹ Congressional Record, October 21, 1998, p. S12876.

³ Congressional Record, October 21, 1998, p. S12876.

² Development and Refinement of the RUGIII Resident Classification System, Preliminary Findings, HCFA NO. 500-96-0003; Task Order #5, October 1, 1998.

Dr. Mark B. McClellan Page 3 July 12, 2005

optimal decisions for beneficiaries, such as focusing on lighter care patients and eliminating respiratory therapists and similar specialty staff.

The situation became more acute as providers began transitioning onto the new system in late 1998. For example, in response to continued provider and Congressional concerns, the CMS Administrator held a PPS Town Hall Meeting focused on the NTA issue on April 23, 1999 where numerous professionals and lawmakers detailed problems in the payment system with respect to NTA. A few months later, on July 30, 1999, CMS issued the final rule for the new payment system, including its responses to comments on the May 12, 1998 Interim final rule, for which the comment period had twice been extended. Responding to comments on the NTA issue, CMS outlined its on-going research to develop a solution. The Agency stated that completion of the research was targeted for January 1, 2000, noting, "If the research supports refinements, we anticipate their implementation in conjunction with the October 1, 2000, update to the PPS rates" (64 Federal Register 41648, July 30, 1999).

Later in 1999, Congress passed the Balance Budget Refinement Act (BBRA). The BBRA provided for 20 percent add-on payments to selected RUG groups as a temporary fix to the NTA problem. The RUG groups selected for the add-ons were those for medically complex patients and three rehabilitation groups where it was also thought many medically complex patients were classified, based on the information available at the time. Congress specified that the add-ons were to remain until the later of October 1,

⁴ "Lawmakers press HCFA on non-therapy ancillaries, DeParle agrees to hold town meeting," *National Report Subacute Care*, February 24, 1999, Pp 1-2. See also: "Testimony of Representative Benjamin Cardin (D-MD) on Skilled Nursing Facility PPS and Quality of Care in Nursing Facilities," April 23, 1999, HCFA Town Meeting.

⁵ The interim final rule implementing the new payment system was published in the Federal Register May 12, 1998, with the comment period scheduled to close on July 13, 1998. On July 13, 1998, the comment period was extended for an additional 60 days. As HCFA explained, "Because of the complexity and scope of the interim final rule and because numerous members of the industry and professional associations have requested more time to analyze the potential consequences of the rule, we have decided to extend the comment period for an additional 60 days. This document announces the extension of the public comment period to September 11, 1998." A correction notice to the original interim final rule was published in the Federal Register on October 5, 1998. Finally, on November 27, 1998, the rule was again opened for another 30-day comment period. The November 27 notice also responded to inquiries regarding how non-therapy ancillaries were accounted for in the rate. HCFA responded that the base rate money was included in the standard nursing payment rate stating further "For the Federal rates associated with urban areas ...43.4 percent of the nursing component is related to non-therapy ancillary costs (including Part B non-therapy ancillary services) and 56.6 percent is related to nursing and social services salary costs. For the Federal rates associated with rural areas ... 42.7 percent of the nursing component is related to non-therapy ancillary costs (including Part B non-therapy ancillary services) and 57.3 percent is related to nursing and social services salary costs."

Dr. Mark B. McClellan Page 4 July 12, 2005

2000, or the implementation of refinements to the case-mix system to account for the costs of NTAs and medically complex patients.

The Abt research, substantially completed in February 2000 did indeed provide compelling evidence of the need for refinements to the payment system to better account for NTA and hence for medically complex patients. However, an effort to implement refinements on October 1, 2000 failed when part of the research conducted initially on a limited sample of cases could not be replicated with a larger, national sample of cases. The part that could be successfully replicated was virtually identical to the change proposed with the current rule. But in 2000 CMS concluded that a single change to the case-mix system (adding more RUGs groups based on patients with both extensive services and rehabilitation) would not serve as an appropriate refinement—a correct judgment in our view, as discussed later.

Since the implementation of the new system, research on its components and effect was undertaken by various federal agencies. By 2000, although there were ongoing disputes about the overall adequacy of total payments, there was agreement across the board that the new system did not account properly for NTAs: MedPAC, GAO, and the Inspector General agreed this was a problem. The Inspector General reported finding access problems to SNF care for medically complex patients with high NTA costs.⁶

When Congress subsequently passed the Benefits Improvement and Protection Act of 2000 (BIPA), the BBRA add-ons were essentially continued, but they were adjusted to correct an anomaly created by adding 20 percent to three rehabilitation classes, in addition to the 20 percent add-ons for medically complex groups. Under that system, some patients with higher rehabilitation use got lower rates than some groups with lower rehabilitation use. In BIPA the add-ons were restructured in a budget neutral fashion to leave 20 percent add-ons for the medically complex patients and place a 6.7 percent add-on on each rehabilitation group. Congress specified that the BIPA add-ons should remain until appropriate refinements were implemented to address the problems of medically complex patients (which meant the identified problems with NTA costs which are especially problematic for medically complex patients). BIPA also required CMS to conduct a study of alternatives to the RUGs case-mix classification system to better account for resource use with the report due January 1, 2005. A substantial part of CMS' contract with the Urban Institute to conduct that research has been devoted to research on RUGs refinements to better account for non-therapy ancillary costs. As of this writing (July 12, 2005), the final Urban Institute report has not been released, nor has CMS submitted the required report to Congress.

⁶ Testimony of George Grob to the Senate Committee on Aging, September 5, 2000.

Dr. Mark B. McClellan Page 5 July 12, 2005

In the current proposed rule, CMS proposes changes ("refinements") to the case mix classification system effective January 1, 2006 and hence also proposes to eliminate the add-ons that Congress established until such time as appropriate refinements addressing identified problems were developed and implemented.

In addition, CMS proposes the annual market basket update to the PPS rates effective October 1, 2005. CMS also proposes to implement a new system for classifying facilities with respect to geographical location for the purpose of assigning an area wage index (used to adjust payments to take into account variations from place to place in the cost of relevant goods and services). The rule proposes to implement the new wage index system for rates beginning October 1, 2005. Comments are solicited on these and other matters.

COMMENTS

I. General

AAHSA's comments below are based on the very limited information CMS has made available about both the research supporting the proposed changes and the methods used to calculate the rates; we believe more information should be made available to the public. In addition, as CMS is aware, the initial proposed rule had several errors in the rate-setting process that had to be corrected. These initial corrections took three weeks and were completed just 13 days before the end of the comment period. We believe that there are still substantial errors in the proposed rule, as we discuss below.

We urge CMS to make necessary corrections to the proposed rule and its rates, to provide fully transparent explanations of each step of the rate-setting process, to release the final Urban Institute report to the public, and to extend the comment period so that more informed analyses and public comments can be provided. We suggest that CMS consider issuing not a final rule as its next step, but an interim final rule with comment.

II. Therapy Index for Rates proposed for Oct 1, 2005 - December 31, 2005

CMS proposes using for rates for October through December 2005 the same therapy index that has been used since 1998. The construction of this index is partially explained in the final rule for the current system, published on July 30, 1999. CMS explains there that the index was constructed from data collected in the 1995 and 1997 staff time measurement studies.

"The therapy staff time was collected over a 7-day period. All time that the therapist, therapy assistant, and therapy aides spent working in the certified nursing unit was accounted for and was apportioned between resident specific and non-resident specific.

Dr. Mark B. McClellan Page 6 July 12, 2005

following the same methodology as was used in the nursing time allocation. All of these collected time study data were used in the development of the indices."

(64 Federal Register 41664, July 30, 1999).

In response to our inquiry regarding differences between the construction of the therapy index proposed for October 1, 2005 and that proposed for January 1, 2006, CMS recently informed us that contrary to the statement above, non-resident specific therapy time was not included in the construction of the therapy index. CMS explained that the decision had first been made during the Case-Mix Payment and Quality Demonstration, as explained in a document staff had found, and then carried into the development of the therapy index for the actual SNF PPS payment system.⁷

AAHSA asks that CMS fully explain construction of the therapy index to be used with the rates proposed for October – December, 2005 and formally correct the previous 1999 statement so that the record is clear.

III. Proposed Refinements to the Case-Mix Classification System

CMS proposes two changes to the case-mix classification system which the agency asserts sufficiently address system problems (lack of ability to pay appropriately for non-therapy ancillaries, especially for medically complex patients) so that the rate cushions added by Congress (6.7 percent for rehabilitation patient and 20 percent for medically complex patients) can be eliminated on January 1, 2006, when the proposed case-mix changes are to implemented. First, CMS proposes adding nine new RUGs classes for patients qualifying for both rehabilitation and "extensive services." Second, CMS increases the nursing index uniformly across all RUG groups by 9 percent, adding an amount to payments equal to approximately 3% of SNF revenues. The Agency states that this uniform allocation acts as a proxy for an adjustment to account for the high degree of variability in non-therapy ancillaries within and across RUG groups.

AAHSA recommends that these case-mix changes not be implemented because CMS provides no evidence that payment accuracy is improved, available evidence suggests the proposed changes are unlikely to meaningfully improve the problems which the add-ons are designed to address and could actually reduce payment accuracy. Further, the proposed changes create additional problems including poor clinical incentives. AAHSA urges CMS instead to complete the planned new time study and the very promising research begun by the Urban Institute. We believe these will enable

⁷ Personal communications with Sheila Lambowitz, July 7 and 8, 2005.

⁸ To qualify for "extensive services," a patient must have the following: ADL sum = 7+; plus one or more of the following: IV feeding (last 7 days), IV meds (last 14 days), Vent/respirator (last 14 days), tracheotomy (last 14 days), or suctioning (last 14 days).

Dr. Mark B. McClellan Page 7 July 12, 2005

CMS to develop and implement a rational, well-conceived solution to the NTA problem for medically complex and other patients using strong research and appropriate data.

Our reasoning is explained in greater detail below.

A. Evidence does not Support the Contention that Payment Accuracy is Improved

CMS asserts that by adding nine new RUGs classes and slightly increasing the nursing index across the board that payment accuracy has been improved sufficiently to render the add-ons no longer applicable. But the proposed rule does not provide evidence that payment accuracy is improved. It is possible that the final Urban Institute report contains that analysis, but it has not been made available to the public.

A.1 Proposed Changes to the Classification System

Review of the original Abt report and the draft Urban Institute report, which AAHSA received through participation on the Technical Advisory panel, suggests the proposed changes to the classification system would not be expected to meaningfully correct the payment accuracy problems that the add-ons address.

In its original research, Abt found that patients receiving Extensive Services had substantially higher NTA costs than others. They note that some of these patients are classified in the rehabilitation groups due to the hierarchical nature of the grouping system. "These high costs suggest that, at a minimum, the payment rate for Extensive Services should be increased (emphasis added). Increasing the payment rate for Extensive Services without further adjustments, however, could reduce provider incentives to provide therapy to Extensive Services without further adjustments. A new category for residents who qualify for Extensive Services and Rehabilitation would alleviate these concerns." Both Abt and Urban thus discuss not one but two changes in a RUG refinement model: changing the classification system (breaking out the Rehab & Extensive Services groups) plus doing something to change the payment system so that payments are better targeted to patients with higher NTA costs.

CMS proposes to create the new RUG groups but does not target increased payments to patients with Extensive Services in a manner correlated with demonstrated higher NTA costs. First, because the Extensive Services category loses its 20 percent add-on, rates for those patients decline on January 1, 2006 (substantially more than do rates for patients in the Rehabilitation groups) – undoing Congress' temporary fix for

⁹ Abt Associates, Variation in Prescribed Medication Costs, Method of Collection and Impact on Skilled Nursing Facility Casemix: Technical Expert Panel Briefing Materials, February 28, 2000, p. 7.

Dr. Mark B. McClellan Page 8 July 12, 2005

those medically complex patients without putting in place a better one. Second, CMS proposes to continue paying for NTA as if those costs were correlated with nursing costs, which research repeatedly shows is not the case.

The one piece of scientific evidence that CMS offers in support of its position that payment accuracy is improved is a report of a slight increase in variance explanation of NTA costs in moving from RUG 44 to RUG 58. The key point is that the dependent variable in the analysis is NTA costs, not the nursing cost index that will actually determine NTA payment. However, the information on variance in NTA costs explained by the RUG 58 system is not a measure of the accuracy of payments for NTA in the payment system proposed by CMS. CMS provides no evidence regarding RUG 53, which it intends to implement; CMS only provides evidence on RUG 58. That is a problem, but not the main one: CMS used the wrong measure of payment accuracy for either RUG 53 or RUG 58.

By contrast, information of the variance explained by the DRG classification system (with respect to total costs) or the RUGs classification system (with respect to nursing costs) both provide good information about the accuracy of the payment systems in which they are used. These examples help illuminate a critical point about assessing the accuracy of a payment system with information about the variance explained by a classification system. The DRG classification system explains about 40 percent of variation among patients with respect to total costs. Weights for the hospital payment system are derived from relative total costs across DRGs. Thus, the variance in total costs explained by DRGs is a good measure of the accuracy of that payment system with respect to total costs. Similarly, the RUGs classification system explains 30-50 percent of the variation in salary-weighted nursing time ("imputed nursing costs") among patients; the weights for the nursing portion of the SNF PPS payment system are derived from relative imputed nursing costs (time study data); thus, the variance in imputed nursing costs explained by RUGs is a good measure of the accuracy of the SNF PPS with respect to nursing costs.

The correlations between RUG 58 and NTA presented by CMS might be evidence of improved payment accuracy (setting aside the facts that the correlations refer to RUG 58, not RUG 53 and the changes are too small to be meaningful) if CMS were to change the payment method, in addition to the classification system, so that the costs of NTA were taken into account. For example, if payments for NTA for each of the RUG groups were targeted say to the mean NTA costs plus two standard deviations (by RUG group) or to weights specifically related to NTA costs. But it is fundamentally irrelevant how well RUG 58 or 53 explains variation in NTA unless CMS changes the payment approach to NTA or it is demonstrated that by moving to RUG 53, the correlation between imputed nursing costs (the nursing index) and NTA is improved. Again, that evidence might be presented in the final Urban Institute report, but it has not been made available to the

Dr. Mark B. McClellan Page 9 July 12, 2005

public. Further, the tiny samples of patients in the available time studies who classify into the new RUG groups proposed make valid analysis with available data improbable.

Before further discussing accuracy problems related to the very small sample sizes, a few more words about the reported correlations between NTA and RUG 44 compared to RUG 58 are in order. The proposed rule mixes apples and oranges in reporting how the percent of variance explained changes from RUG 44 to RUG 58, citing as the RUG 44 coefficient an Abt number (4.1 percent) but citing Urban numbers (9.5 percent and 10.2 percent) for the RUG 58 coefficients. Doing so creates the impression that moving from RUG 44 to RUG 58 more than doubles the explanation of NTA costs. But Abt and Urban used different databases, different analytical techniques, and—most importantly—unstated though likely different—trimming cut-points. All of these differences—particularly trim points—can account for the difference between Abt's original number and Urban's final ones. Some known differences among study approaches are summarized in Exhibit I.

The correct way to compare the change in variance explanation attributable to a change in RUG models is to look at the coefficients related to each model in the same study. Thus, the relevant comparisons for Urban's work are a change from 5.3(RUG 44) to 8.5 (RUG 58) from their 2004 draft report and a change from 6.4 (RUG 44) to 9.5 or 10.2 (RUG 58) as reported in the proposed rule (70 Federal Register 29076, May 19, 2005).

Notably, the r-squares reported for the Urban Institute research in the proposed rule are both *higher* than those reported in the last document that had any degree of public scrutiny (i.e., by the Technical Advisory Panel)—the draft report of June 2004. It would be helpful to know what accounts for that difference. We suspect that trim points were changed because we also observe differences in the reported "% of high cost cases correctly predicted," but again ask CMS to make to relevant research available to the public so that this can be understood.

The main point demonstrated by the data in Exhibit I is this: regardless of the study details, both RUG 44 and RUG 58 are poor predictors of NTA costs. Moving from RUG 44 to RUG 58 increases variance explanation by 3-4 points, but the variance explanation is still poor.

Dr. Mark B. McClellan Page 10 July 12, 2005

Exhibit I Comparison of Studies Predicting Non-Therapy Ancillaries With RUG-44 & RUG 58 Models

	ABT 2000 for CMS NPRM	Fries/UI 2001 Validation For CMS	Fries/UI 5/7/2003 Presentation to TAP	Urban Institute June, 2004 Draft Report	NPRM 2005
R-Square RUG-44 RUG-58 % high cost correctly	0.041 0.080	0.047 0.075	0.041 0.059	0.053 0.085	0.064 0.095-0.102
predicted RUG-44 RUG-58 Technical Details				0.193 0.256	0.314 0.376
Dep. Var.	Cost	Log (cost)	Log (cost)	Cost	Cost
Data Set	5 States 1995-97	National- CMS; 1999	DataPro 1999	DataPro10% 2001	DataPro10% 2001
Cases			5-Day Admission only	All valid	All valid
Trim Points	?????	?????	Mean+2SD Trunc@\$444.50	77777	77777

In summary, changes in NTA variance explanation between a RUG 44 and a RUG 58 model do not provide evidence that CMS' proposed case-mix changes improve payment accuracy for at least two reasons. First, changes in variance explanation of NTA costs between the two models is no more than 3-4 points on a poor base. Second, actual payment for NTA costs continues to be made on the bases of nursing weights, with no evidence that the correlation between this and NTA costs is improved with the addition of nine new RUG groups.

The proposed changes also appear to decrease payment accuracy for those medically complex patients not receiving rehabilitation. Elimination of the 20 percent add-ons for the medically complex patients, including Extensive Services patients, who do not get rehabilitation, reduces rates for these medically complex patients relative to non-medically complex patients receiving rehabilitation: This change is completely

Dr. Mark B. McClellan Page 11 July 12, 2005

contrary to evidence provided in the draft Urban Institute report. An important table from that June 2004 is replicated as Exhibit II, found on the following page.

In Exhibit II on the following page, the third column may be interpreted as the difference in dollars of average NTA costs for patients in a particular RUG group, compared to average NTA for all patients. For example, average NTA costs for the highest RUG group in the table ("XUC" which is "RUX" in CMS' proposal) are \$15 higher than NTA costs for the average patient. Note that NTA costs for the medically complex patients in SE1, SE2, and SSA RUG groups are all considerably higher than NTA costs for the highest group (the NTA costs are higher than the overall mean by \$30.40, \$59.30, and \$39.9 respectively). Note also that NTA costs (relative to the mean) for the rehabilitation groups without Extensive Services (e.g., RUC, RUB, RUA, etc) are all less than the mean, while NTA costs for patients in medically complex groups SE1, SE2, SE3, and SSA are all greater than mean NTA costs. That means to improve payment accuracy for those medically complex patients with respect to NTA (the identified problem), a new system would increase payments for those medically complex patients, relative to the non medically complex rehabilitation patients. But CMS' proposed changes do the opposite: on January 1, 2006, payments are to be reduced more for the medically complex patients than for those in the plain rehab categories, reducing the difference in payments when the data show that differential should be increased.

We take this opportunity to note especially proposed rate changes for two rehabilitation RUG groups. CMS proposes to <u>increase</u> on January 1, 2006 (compared to 2005 rates) rates for RMA and RLA by 3.42 and 1.55 percent, respectively. Rates for all other RUG groups will decline. Those for medically complex patients not getting therapy will decline by 15 to 16 percent. These anomalies may be due to errors in the therapy index, but in any event require explanation.

There is further evidence of a likely reduction in payment accuracy in the small samples from the available time studies. One part of the RUG 44 system which is known to work well is that it has repeatedly been shown to do a good job of explaining variations in observed nursing and therapy staff times (from time studies). Further, there is evidence from state Medicaid data that the nursing index correlates reasonably well with actual nursing costs at least in some states. There is no evidence provided in the proposed rule regarding how the predictive power of these fundamental parts of the RUG system change with the proposed introduction of the nine new classes. It is possible that in rushing to implement a new classification system, based on incomplete analysis of NTA costs, the baby will be thrown out with the bath water. The "baby" in this case being the parts of the system, particularly the relationship between the classification system and nursing costs (hence payments), that actually work. While no analysis of this issue is presented, the very small sample sizes for the new RUG groups raise considerable concern.

Variable	Mean (sample %)	Regression of NTA per dien on Variable		
	- 1	Coefficient(d iffence in \$ from mean)	R-square	
Rehabilitation and Extensive				
Services				
XUC	0.002	15.1	0.000	
XUB	0.007	0.15	0.000	
XUA	0.001	-16.9	0.000	
XVC	0.006	15.8	0.000	
XVB	0.027	-1.86	0.000	
XVA	0.004	-7.10	0.000	
XHC	0.069	24.5	0.005	
XHB	0.066	12.2	0.001	
XHA	0.001	9.28	0.000	
XMC	0.026	43.4	0.007	
XMB	0.040	32.6	0.006	
XMA	0.001	31.6	0.000	
XLB	0.001	33.7	0.000	
XLA	0.001	57.1	0.000	
Rehabilitation				
RUC	0.004	-29.5	0.000	
RUB	0.022	-34.3	0.003	
RUA	0.009	-34.3	0.001	
RVC	0.010	-30.7	0.001	
RVB	0.069	-35.4	0.009	
RVA	0.037	-30.6	0.004	
RHC	0.082	-19.9	0.004	
RHB	0.102	-23.6	0.007	
RHA	0.063	-9.68	0.001	
RMC	0.026	-19.4	0.001	
RMB	0.061	-20.6	0.003	
RMA	0.037	-2.60	0.000	
RLB	0.001	-21.3	0.000	
RLA	0.002	-14.6	0.000	
Extensive Services				
SE1	0.003	8.11	0.000	
SE2	0.064	30.4	0.008	
SE3	0.041	59.2	0.021	
Special Care				
SSC	0.008	-3.87	0.000	
SSB	0.012	-4.28	0.000	
SSA	0.036	39.9	0.008	
Clinically Complex				
CC2	0.001	-30.3	0.000	
CC1	0.004	-14.0	0.000	

Dr. Mark B. McClellan Page 13 July 12, 2005

CB2	0.003	-20.2	0.000
CB1	0.012	-19.4	0.001
CA2	0.004	- 9 .25	0.000

The RUG system assigns a nursing weight to each class that reflects the relative costliness of nursing for one type of patient compared to another, based on data collected in time studies; a different therapy index is also assigned to each group reflecting the relative costliness of selected types of therapy. Those weights, in turn, through a series of calculations, ultimately determine the dollar value of payments for each type of RUG patient day. But tiny samples of patients in the time studies mean that the size of differences observed among groups in average time could be random, making the size of payment rate differences among different RUG groups inaccurate. There is no assurance that the observed relative times are stable. Sample sizes for the new groups for which we have information are shown in Exhibit III.¹⁰

Exhibit III
Sample Size for Cases from the 1995 and 1997 Time Studies Used to set the Nursing & Therapy Indices for Rates Proposed for January 1, 2006

Proposed New RUG Group	Number of Cases in Time Studies
RUX	9
RVX	7
RHX	26
RHL	16
RHX	45
RHL	31
RLX	5

In all but two of the groups, proposed rates are being set on the basis of time studies done on fewer than 30 cases. For three groups, payments for millions of Medicare days are being set based on what happened to fewer than 10 patients in a small number of SNFs, nine to twelve years ago! It is difficult to believe that this represents an improvement in payment accuracy.¹¹

Sample sizes for the groups shown can be identified from a document on the CMS WEB site: "Nursing and Therapy Minutes used in Calculating Preliminary Rates: April 10, 2000 Federal Register PPS Update." Sample sizes for the two missing new RUG groups (RUL and RVL) cannot be identified from that document.

¹¹ The same time data are used to calibrate rates today under the RUG 44 system. But because there are fewer subcategories, the relevant sample sizes are much larger. Further, there are numerous studies documenting the stable correlation between RUG 44 and observed nursing time. There are no studies of nursing and therapy time for RUG 53/58 of which we are aware other than that with the small sample sizes noted above.

Dr. Mark B. McClellan Page 14 July 12, 2005

Although CMS did use the samples identified in Exhibit II for both the therapy and the nursing index, we believe that that was the wrong sample to use for the therapy index, as discussed below. The correct sample to use for the therapy index will likely have even fewer sample cases.

CMS is planning to do a new time study, which is an excellent and necessary plan. But accuracy problems with the small samples available now cannot be ignored; we believe they provide clear evidence the proposed changes for January 1, 2006 will likely decrease payment accuracy. Further, the relationship between NTA costs and nursing costs (as imputed from the time study) cannot even be assessed without an accurate time study. So, to establish this new RUGs classification system before the required time study is done is putting the cart before the horse.

A.2 Increasing the Nursing Index (to add 3% back into payments)

Despite asserting that moving to RUG 53 meaningfully improves the accuracy of payments for NTA, CMS apparently recognizes that RUG 53 and the payment system proposed very poorly targets payments to account for NTA. CMS repeatedly points out in the rule (at least three times, by our count) that both within and across RUG group variance in NTA is quite large. This is the same thing as saying that RUG 53 does a poor job of accounting for variance in NTA costs. For example, CMS notes: "We have found a high degree of variability in non-therapy ancillaries not only within but across RUG groups...an individual patient who is classified into a less intensive RUG may nevertheless be significantly more expensive to treat in terms of non-therapy ancillaries than an individual patient in a more expensive RUG....The addition of the 9 new groups does not by itself, compensate for this discrepancy" (emphasis added; 70 Federal Register 29079, May 19, 2005).

To address this *variation*, CMS applies a *constant* small increase in the nursing index across all RUG groups. The size of the factor (about 3 percent of total revenues) is said to have been selected because that is the size of the outlier portion of the inpatient rehabilitation hospital payment system (which is, like all outlier payments, targeted to high cost cases, not spread across all cases). But if similarity to another post acute payment outlier system is the criteria, we believe the 8 percent outlier pool used in the LTC-hospital Medicare payment system is a better referent because of the wide variation in NTA costs within and across groups and because the SNF PPS has no true outlier payment provision.

We appreciate the fact that CMS was looking for a way to put back some of the money lost by the elimination of the add-ons. But the add-ons are tied to the accuracy of payments, particularly for NTA costs. The more poorly the payment system is able to

Dr. Mark B. McClellan Page 15 July 12, 2005

target payments appropriately, the wider the spread needs to be in "cushion" payments (i.e., an added constant to the nursing index or overall add-ons) to make up for that problem. For example, imagine a blindfolded painter faced with the task of assuring that most of 100 randomly placed dots on a wall be covered over by paint. Since he can't see the dots (can't target the paint), he needs to cover the entire wall. This is obviously inefficient, illustrating why CMS needs to complete the promising research begun by the Urban Institute and develop a SNF PPS that properly accounts for variations in costs among patients, before removing the add-ons. A much smaller "cushion" is no solution to a payment system change providing no meaningful improvement in the problem, which the add-ons are designed to address.

A.3 Better options to pay accurately for NTA costs

At the June 2004 Technical Advisory panel meeting, researchers from the Urban Institute presented evidence of a way to revise SNF payments that would actually improve the accuracy of payments substantially more than RUG 53 could possibly do. In brief, Urban found a set of variables (patient characteristics) that explained 13-21 percent (depending on the model) of NTA costs. This set of variables could be used to create an index to adjust a standard NTA payment amount that would then be added to a Basic RUG payment. This would not involve creating additional groups.

We were thus very surprised to read in the proposed rule CMS' statement that while options other than the one selected were explored, "none of these alternatives offered a significant improvement over the RUG 53 model in accounting for the variability of non-therapy ancillary costs" (70 Federal Register 29163, May 19, 2005). It is possible that something happened in the analyses that took place after the June 2004 meeting that in essence wiped out the earlier findings. Making these findings available for public consideration is obviously critical.

B. Clinical concerns and related reasons why AAHSA recommends the proposed system changes not be implemented

AAHSA is very concerned about the consequences for patient care if CMS were to implement the changes it proposes in this rule. We are certain that CMS will be equally concerned when the problems are brought to its attention. The new system creates an intense financial imperative for SNFs to find patients who qualify for the nine new RUG groups and these groups are defined by a small set of unsettled, troublesome items from the MDS. The combination of circumstances could hardly be worse for patient care.

Classifying patients into one of those groups requires that they have these characteristics:

- A sufficient amount of therapy either estimated or—in the case of the Ultra and Very High group—actually provided and
- They qualify for Extensive Services, which requires:
 - An ADL score greater than 7 and
 - At least one of the following: In the last 14 days (even if that was in the previous hospital stay) IV medications, vent/respirator care, tracheotomy, or suctioning; or IV feeding in the last 7 days (even if that was in the hospital).

Since the current system also uses these clinical items to classify patients for Extensive Services and since the rehabilitation groups pay the most, there could currently be financial incentives to find these types of patients. Why is the proposed new system different? First, the strongest incentive in the current system is for rehabilitation patients over clinically complex ones. So, under the current system, there is no particular incentive to find Extensive Services patients. Indeed the proportion of those without rehabilitation has been declining. Under the proposed system, however, there will be not only new pressure to find Extensive Services patients who qualify for Rehabilitation, but the financial pressure to find a particular type of (previously rare) patient will be far more intense than anything going on now.

It is only by finding sufficient patients to fit the new groups that providers will be able to avert largely untenable financial circumstances. On average, homes that are not able to find any of these patients will have revenues beginning January 1, 2006, about 7-8 percent lower in real terms than now. These losses are the equivalent of having new rates set at "market basket minus 7-8 percent." It is helpful to think of the situation that way, because when MedPAC recently reviewed SNF Medicare-specific margins and other financial circumstances, it concluded that it would be appropriate to keep SNF rates level (that is, MedPAC recommended essentially "market basket minus 3." A zero update would present a far different financial circumstance than CMS is proposing. Thus it is clear how intense will be the pressure for homes to find sufficient numbers of the new RUG group patients to mitigate their losses.

It became increasingly clear as our members informed us of the projected impact of the proposed new system that patients in the new RUG groups are not evenly distributed; many of our members—even those providing care to very clinically complex patients (but who too frequently for the new system are not suitable for therapy)--noted that they had no qualifying patients now and realistically expected they would have few. Many mentioned the issue of how this depends too much on local hospital practices. These very strong and peculiar financial incentives are the context for evaluating the clinical conditions that define entry into the new RUG groups.

Dr. Mark B. McClellan Page 17 July 12, 2005

As noted above, both the therapy criteria and the Extensive Services criteria are very troublesome in the context of the proposed payment system. Consider first the issue of therapy. As Dr. Kramer points out in the draft Urban report, there is little scientific evidence to help clinicians judge the appropriate "dose" of therapy for particular situations. Well-intentioned and well-trained professionals can differ considerably. Adding intense financial incentives to the mix substantially increases the probability that clinically inappropriate amounts of therapy will be provided to SNF patients. Even if "excess" therapy is only infrequently dangerous for patients, diverting resources to this aspect of care unnecessarily reduces the resources available for nursing care, for example, which may be more important in many instances to quality.

The criteria for Extensive Services are also extremely problematic in the context of this proposed payment system. According to the draft Urban Institute report, by far the most common clinical reason patients qualify for Extensive Services is that they meet the criteria of having had IV medications in the last 14 days, most commonly because they had that in the hospital. Nearly 60 percent of patients, according to the Urban Institute, meet the MDS criteria (which includes an allowable look back) for IV medications in the last 14 days, but in only 8 percent of cases could Urban find evidence from the SNF claim that IV medication was provided in the SNF.

If the proposed system were implemented then SNFs' ability to survive financially in many cases would become dependent on local hospital practices, creating perverse incentives for patient care. One need not suppose that providers (either in hospitals or SNFs) are a larcenous lot willing to stick IVs in patients to increase profits. Mistaken concepts about payment and well-intentioned thoughts about how to help patients qualify for needed financial benefits, however, can induce clinically irrational behavior. Just as the statement that "your DRG ran out" rapidly became an explanation to patients for fast discharge from a hospital after the implementation of the hospital PPS, so is it easy to imagine the misconception developing that "Medicare doesn't pay for SNF care for patients who didn't have an IV in the hospital." Even if not one unnecessary IV were implanted as a result of the proposed new system, it is perverse to tie SNFs' financial viability to local hospital practices, when differences in those practices from place to place may have virtually nothing to do with actual differences among patients with respect to care needs in the SNF.

Does the fact that a SNF patient had IV medications (or feeding) in a hospital (but not in the SNF) mean that that patient is more costly than others in the SNF? This is a critical empirical question to answer <u>before</u> implementing a new payment system that heavily depends on the answer for payment accuracy and appropriate clinical care. There are two types of costs that are particularly important: nursing time and NTA costs. For neither type of costs do we currently have sufficient information to chance such a radical change to the SNF case-mix classification system as is proposed.

Dr. Mark B. McClellan Page 18 July 12, 2005

When the RUG system was developed, relatively few patients qualified for Extensive Services and especially few qualified for both Rehabilitation and Extensive Services. Notably, less than 2 percent of the patients in the 1995 and 1997 time studies qualified for both Rehabilitation and Extensive Services, despite an effort by the researchers to find study homes that cared for more medically complex patients. In 2001, however, nearly 10 times that proportion (about 18 percent) of SNF patients would qualify for both Extensive Services and Rehabilitation, according to CMS. Does this represent more of the same type of patient or a *different* type of patient than those studied previously? In previous time studies, patients qualifying for Extensive Services (including those identified via the look back provision) demonstrably did require more nursing time *in the SNF* than others. But we cannot know what the situation is now without a more recent time study.

The second issue regards ancillary costs. Here it is critical to understand important findings by the Urban Institute researchers. Exhibit IV, below, replicates a table from their draft report. The data indicate that NTA costs are only substantially higher for patients with IV medication use when that is documented both in the MDS and on a SNF claim. For those cases where there is only documentation in the MDS—and particularly for the 5-day and 14-day assessments—NTA costs are considerably less. This suggests, but does not confirm, that NTA costs may not be higher for patients' whose IV medication use occurred in the hospital but not the SNF. Urban Institute researchers were careful to note that there are likely errors in both types of documentation and that further research would be necessary. Using only those cases with clear documentation of Extensive Services actually in the SNF did, however, allow the researchers to develop a way to explain 21 percent of variance in NTA costs.

Thus, to improve payment accuracy at least for NTA, it may be useful to have a clear indicator in the MDS (or elsewhere) to distinguish some services (e.g., IV medications) which are actually provided in the SNF, even if it is important for other purposes to retain the look back. The critical and missing information that CMS needs before implementing a system based on unproven ideas regarding costs and RUG groups can be collected in the planned new time studies. In those studies both staff time and ancillary costs should be assessed accurately for patients and both forms of assessing service use (both with and without the look back) should be used. This will provide the information needed to make a rational decision.

Urban Institute Data Showing NTA Costs for Patients with different types of documentation of IV Medication Use

Average NTA stay cost per diem by presence of MDS and claim report, by assessment number [Source: Urban Institute Draft Report, June 2004]

Assessment	Neither MDS assessme nt or claim	MDS only	Claim only	MDS assessme nt and claim	N
IV Medication*				<u> </u>	,
5 day	43.5	53.6	76.3	136	16,074
14 day	34.6	53.0	61.2	124	9,734
30 day	32.0	71.6	58.0	117	4,609
60 day	31.3	75.1	57.9	[99.0]	1,321
Respiratory Problem**					
5 day	47.3	64.5	95.3	127.8	16,083
14 day	37.1	48.9	76.8	103.2	9,740
30 day	33.2	44.4	60.9	105.6	4,612
60 day	30.7	36.4	54.3	[119.7]	1,322

^{*}Indicates IV Medication reported on MDS for the given assessment and/or a claim for IV therapy or solution for the stay.

Note: Brackets indicate categories with fewer than 25 cases in the category.

AAHSA's comments on the matter of the look-back and estimated therapy are provided in the total context of the information discussed above. First, our members strongly support maintenance of the current look-back and estimated therapy provisions which they note are essential for appropriate clinical care—the ultimate reason for the MDS. So if these two items were to be changed for payment purposes, then that should be done by the addition of a new "payment item only" question. There are some good reasons for considering eliminating both the look-back (discussed above) and estimated therapy provisions for items related only to payment, although a rational decision could not be made without the further research identified above. Finally, however, there is the matter of SNF revenues. We believe that if CMS implements the proposed new system it will assure tremendous pressure to keep both the look-back and the estimated therapy provisions under any circumstances because the entire new financial system for SNFs

^{**}Indicates tracheotomy, vent or oxygen (with conditions) reported on MDS for the given assessment and a claim for pulmonary or respiratory for the stay.

Dr. Mark B. McClellan Page 20 July 12, 2005

will have been linked to those two troublesome technical provisions. In light of those circumstances, AAHSA recommends the following.

AAHSA recommends that CMS not create new RUG groups based on extensive services and rehabilitation; but if that is done it should not occur until after appropriate data from the new time study are collected and a principled decision is made about the advisability of changing the assessment protocols for items used for payment purposes with respect to the "look-back" and "estimated therapy" procedures. AAHSA further recommends that the current look-back and estimated therapy protocols be kept as they are on the current MDS for clinical reasons. Finally, AAHSA urges CMS to assure that if changes are made to those assessment protocols that this is done so that the effect is budget neutral.

To clarify the last recommendation with regard to budget neutrality, we recommend that this be done in a manner similar to what CMS has attempted to do in its proposed move from RUG 44 to RUG 53. A change deemed valuable for its own sake, but not intended to reduce aggregate payments, can be accomplished by re-weighting the payment system. But this needs to be done before substantial incentives to alter behavior related to the potential change are put in place: in brief, it will be extremely difficult to accomplish changes in the protocols—however sensible that be--for reasons related to both technical matters and stakeholder financial concerns unless CMS does this <u>before</u> changing the RUG system.

D. Inaccurate Construction of the Therapy Index for January 1, 2006

We believe that the therapy index incorporated in the proposed rates is inaccurate, necessitating its recalibration and subsequent recalculation of all of the other rate elements that are related.

We believe that in constructing the therapy index for January 1, 2006, CMS likely has incorrectly selected cases from the 1995 and 1997 time studies. For the therapy index used since 1998 and proposed for October- December 2006, CMS identified the cases from the time study to be used according to the number of therapy minutes actually observed being provided to the patients. But in constructing the therapy index for the rates proposed for January 1, 2006, CMS selected cases from the time study based on what was written on the MDS assessment. This results in a proposed new therapy index that is not only inconsistent with past policy (and the policy proposed for October – December 2005 rates), but also one whose sample base does not consistently qualify for the rehabilitation groups into which they are placed because they are not receiving enough therapy. Our evidence is outlined below.

Dr. Mark B. McClellan Page 21 July 12, 2005

The resident-specific minutes used to construct the therapy index first used In 1998 and proposed for rates from October through December 2005, and the relevant sample size for each group are shown below in Exhibit I.

Exhibit I
Sample Size and Mean Therapy Minutes by RUG Groups for Therapy Index
for Proposed Rates for Oct-Dec, 2005
Based on Data from 1995 & 1997 Staff Time Measurement Studies

Rehabilitation Group	Total Therapy Minutes in the last 7 days Required to be Classified into this Rehab Group	Sample size	Ave Total Therapy Min/Day	Minutes/Day X 7
Ultra High	720	195	155.0	1,085.0
Very High	500	179	99.4	695.8
High	325	264	67.8	474.6
Medium	150	431	55.4	387.8
Low	45	64	34.3	240.1
Total		1133		

Source: "SNF PPS Therapy Index" (file name = snfppsti.);

http://cms.hhs.gov/providers/snfpps/snfpps rates.asp.; accessed 5/21/05.

Note that the average minutes for total therapy for each group exceed the minimum minutes required for a resident to be classified into the relevant Rehabilitation RUG groups. This is definitely not the case for the sample used to construct the proposed therapy index for the new system, even though the data are from the same 1995 and 1998 staff time measurement studies. Consider, for example, the differences for the Ultra and Very High RUG groups.

Old Index Ultra Groups: Total therapy minutes =155/day (X 7 = 1,085) New Index Ultra Groups¹²:

RUX = 84.22/day (X 7 = 589.54)

RUL = 126.14/day (x 7 = 882.98)

RUC = 109.53/day (X 7 = 766.71)

¹² "Preliminary Analysis of Case Mix Indices," added to the CMS "Case-Mix Refinement" Web site in late June 2005, following revision of the method for computing the therapy index for rates proposed for January 1, 2006.

Dr. Mark B. McClellan Page 22 July 12, 2005

RUB = 105.92/day (X 7 = 741.44)

RUA = 95.17/day (X 7 = 666.19)

Old therapy Index Very High Groups: Total therapy minutes = 99.4/day (x 7 = 695.8)

New therapy index Very High Groups

RVX = 54.14/day (X 7 = 378.98)

RVL = 57.58/day (X 7 = 403.06)

RVA = 57.53/day (X 7 = 402.71)

RVC = 65.65/day (X 7 = 459.55)

RVB = 65.74/day (X 7 = 460.18)

Note that in every case the new therapy index minutes are substantially lower than the old therapy index minutes. Furthermore, for most of the new therapy index groups the sample residents are receiving on average too few therapy minutes to qualify for the Rehabilitation group into which they have been placed.

The answer to this mystery appears to lie in a 1997 CMS memo that we were fortunate to find in our files on July 9. In a memo entitled "Nursing Home Case-Mix and Quality Demonstration: Response to Therapist Working Group Member Question," Elizabeth Cornelius (CMS Project Officer for the demonstration) explains that among the sample cases in the time studies, the therapy minutes recorded for a resident on the MDS do not consistently agree with the therapy minutes observed and recorded by the researchers for that resident; where they differ substantially it is most often the case that the observed minutes are fewer. Thus, "the rehab analysis to establish subcategories and the index scores for rehabilitation services used only the time recorded [by the researchers]..." Ms. Cornelius also confirms in this memo that the therapy index is based on resident-specific time and does not include non-resident specific time. Table 2 in this memo shows the data used from the 1995 time study to construct the therapy index and is clearly labeled to indicate that sample cases were selected on the basis of

¹³ Elizabeth Comelious, "Nursing Home Case-Mix and Quality Demonstration: Response to Therapist Working Group Member Question," February 18, 1997.

Dr. Mark B. McClellan Page 23 July 12, 2005

the therapy minutes recorded by the researchers, not on the basis of the minutes recorded on the MDS. 14

III. Proposed Revisions to the SNF PPS Labor Market Areas

A. Hospital-based Wage Index Used for SNFs:

Since the introduction of the SNF PPS in 1998, CMS has used Medicare inpatient hospital wage data to develop a wage index for defining local market differences for all SNFs. In the SNF PPS proposed rule notice for FY 2006 (70 FR 29091, May 19, 2005) CMS proposes to continue using the Medicare inpatient hospital wage index for the SNF PPS.

The hospital wage index does not as appropriately adjust for variations in SNF labor costs across geographic areas as a SNF-specific one would. Researchers have confirmed that the hospital wage index is a relatively poor predictor of labor cost differentials for SNFs across geographic areas, in part because hospital staff mix and wage differentials differ from SNFs.¹⁵

In addition, the lack of a SNF-specific wage index prevents SNFs from being able to take advantage of a reclassification option that hospitals have which mitigate (for hospitals) the effect of wage index imperfections on payment accuracy. For hospitals, if the area wage index in an urban area of a State is less than the area wage index for hospitals located in rural area, the hospital is allowed to apply for reclassification under sections 1886(d)(8) and (d)(10) of the Social Security Act. Section 315 of the BIPA 2000 also authorizes the Secretary to establish a reclassification option for SNFs in the same situation; however, this reclassification provision for SNFs cannot be implemented until the Secretary has established a wage index specific to SNFs. This is particularly problematic for SNFs in larger rural areas that have a wage structure more aligned with neighboring smaller urban areas.

Seeking more accurate payments, AAHSA has repeatedly recommended that CMS develop a SNF-specific wage index. In 1994, Congress mandated that this be done. In 1999, MedPAC recommended that the "Secretary develop a wage index based on SNF

¹⁴ The numbers in this table exactly match up with the numbers reported by CMS as having been used from the 1995 time study (in combination with data from the 1997 time study) to construct the therapy index used since 1998.

¹⁵ Kathleen Dalton and Rebecca Slifkin, "Rural-Urban Issues in the Wage Index Adjustment for Prospective Payment in Skilled Nursing Facilities," 2003.

Dr. Mark B. McClellan Page 24 July 12, 2005

data and use it to adjust payments for those facilities' services." In BIPA 2000, Congress reaffirmed the mandate.

Despite that, CMS has yet to construct a SNF specific wage index. We appreciate that the data currently collected are problematic and urge CMS to put in the required effort (we pledge to help) to get accurate reporting on SNF wages and occupational mix. As CMS remembers it took several years before the hospital data could be used.

AAHSA recommends that CMS improve the collection of reliable SNF wage data and implement the Congressionally mandated SNF-based wage index to improve the accuracy of Medicare SNF payments.

B. The New CBSA wage index

On June 6, 2003, the Office of Management and Budget (OMB) issued bulletin No. 03-04 announcing revised definitions for the Statistical Areas. CMS is proposing to adopt OMB's new labor market designations for SNF payments, effective January 1 2006. Although AAHSA agrees with CMS that the new OMB geographic areas (CBSAs) reflect the most up to date information used to develop new social and economic market regions (with some exceptions that are intended to be remedied with the reclassification provision), AAHSA is concerned with the overall magnitude of the impact this provision will have on SNFs, particularly those facilities that lose more than 5 percent of their wage index value with the implementation of this new designation. We are also concerned that because SNFs do not have a SNF-specific wage index, there will be no recourse for those SNFs that get misplaced in market labor regions that warrant reclassification.

AAHSA recommends that CMS phase-in the new CBSA wage index over at least 3 years. During that phase-in the wage index should be a blend of the old wage index and the new one, with an increasing reliance on the new one in each successive year (e.g., 25%, 50%, 75%, then 100% of the CBSA)

In addition, AAHSA recommends that CMS establish both floor and ceiling wage index change targets for at least the first year. The specific targets would have to facilitate compliance with budget neutrality requirements, but optimally they would be something like a floor of -5% and a ceiling of +10%.

Our reasons are given below.

¹⁶ MedPAC, *Report to Congress*, March 1999, p. 89.

Dr. Mark B. McClellan Page 25 July 12, 2005

CMS noted in the May 19, 2005 SNF PPS proposed rule that it had considered some options for SNFs to adapt more easily to this new classification and to mitigate the resulting adverse impact on those SNFs that experience large losses in their wage index value. The options included a hold-harmless policy, a one-year transition with a blended wage index for all providers, and a one-year transition with a blended wage index limited to providers that would experience a decrease in their FY 2006 wage index under the new CBSA definitions. Subsequently, all these options were abandoned by CMS given that only a minimal number of SNFs (4 percent) would experience a decrease of 5 percent or more in the wage index. CMS's argument was that the budget neutrality provision would require the majority of providers (61 percent of facilities that receive an increase in their wage index) to subsidize those that loose in this new designation by accepting lower payment rates for the benefit of only a small number of SNFs.

AAHSA understands CMS's concerns; however, AAHSA believes that the same rationale used by CMS to discard these potential options could very well be applied for promoting similar solutions that would require a more equitable redistribution of resources from those who experience large increases in wage index to those who experience large decreases in their wage index. Since a minimal number of SNFs (4 percent of facilities) would experience a decrease of more than 5 percent in the wage index, it is reasonable to assume that a relatively larger number of facilities that would receive sizeable increases in wage indexes would each experience only modest and reasonable payment decreases to subsidize those smaller number of facilities that experience substantial decreases in payment due to reduced wage index values.

Counties such as Culpepper and King George Counties in Virginia would experience the highest losses totaling 27 percent of their wage index value with the implementation of this new system. Warren County, New Jersey would experience a loss of 19 percent. Madera County, California would experience a 16.4 percent reduction in wage index. Cayuga County, New York, would experience a 14.1 percent drop in wage index. We have heard from our members that wage index losses similar to these could very well affect their financial sustainability and their ability to continue to provide the higher quality of care they are now able to offer their residents. By contrast, facilities in some other places would receive amazing windfalls. (for example, San Benito County in California, that would experience a gain in wage index of 42.2 percent).

Since this issue involves a conflict of interest between two sets of SNFs, we referred it to the AAHSA Ethics Commission for consideration. The Commission recommended an approach which AAHSA incorporates in its recommendations to CMS. The Commission unanimously decided that AAHSA should urge CMS to adopt a position that would distribute the impact of this new OMB provision by supporting those homes (and their residents) that would be most vulnerable, despite it meaning a temporary delay in the gainers' realizing full benefits. With this purpose in mind, the Commission

Dr. Mark B. McClellan Page 26 July 12, 2005

believes that a 3-year phase-in period with a "floor" and "ceiling" wage indexes should be considered for FY 2006. The AAHSA Ethics Commission believes that this is a matter of equitable redistribution and is the best approach to solve significant disparities among SNFs located in different regions of the country.

IV. Consolidated Billing

BBA required CMS to develop a PPS that consolidates the billing for all needed services under one payment rate with some specified exceptions. BBRA expanded the list of exceptions by excluding from consolidated billing for SNF PPS four categories of services (chemotherapy items, chemotherapy administration services, radioisotopes, and customized prosthetics) and authorized CMS to identify the specific codes that represent high cost and low probability services. In addition, BBRA authorized CMS to periodically review the specific codes and to add services as deemed appropriate. In this proposed rule, CMS has requested suggestions of services that fall within one of the four categories and that meet the standards of high cost and low probability within the SNF setting that should be added to the list of services excluded from SNF PPS consolidated billing.

1. Chemotherapy Items and Administration, Radioisotopes, and Customized Prosthetics – Residents requiring chemotherapy require more than just administration of chemotherapy drugs. Residents also require administration of other drugs to counteract the side affects or to enhance the potency of the chemotherapy drug. Examples of services and drugs related to chemotherapy that should be added to the list of codes that are excluded from SNF PPS are J1260, J9202 and Q0136. These services are high costs that range between \$500 to \$1200 per service and low probability of utilization. Administration with IV infusion (90780 or 90781) should also be excluded from SNF PPS.

AAHSA recommends that CMS exclude drugs (i.e. J1260, J9202 and Q0136) and administration of IV infusion (90780 and 90781) that accompany chemotherapy.

2. Other Services that Should be Excluded from SNF PPS – AAHSA would like to take this opportunity to mention to CMS that other services provided to SNF residents also meet the conditions of being very high costs and having a low probability of utilization. CMS identifies codes for services that are outside the domain of a SNF and are excluded from SNF PPS when performed in a hospital. In addition to the services CMS has identified, AAHSA would like to suggest other services that deserve similar consideration.

- a. PET Scans Many of our members mentioned that PET scans and the administration of drugs related to PET scans should be excluded from SNF PPS as hospital-based services.
- MRA -Magnetic resonance angiography is a hospital-based service outside the domain of a SNF. Many individual codes are for high cost and low probability services.
- c. Nuclear Medicine Nuclear medicine includes an extensive list of codes for nuclear medicine services to various body systems. Many of these services are very high cost and low probability of utilization that should be excluded from SNF PPS.
- d. Ultrasonic Procedures and Duplex Scan Ultrasonic procedures and duplex scans are performed in conjunctions with other services. Many of these services are very high cost and low probability of utilization that should be excluded from SNF PPS.

AAHSA recommends that CMS consider additional services (PET, MRA, nuclear medicine and ultrasonic procedures) as hospital-based that are outside the domain of a SNF and excluded from SNF PPS consolidated billing.

V. Qualifying Three-Day Inpatient Hospital Stay Requirement

AAHSA applauds CMS' willingness to consider observation days in beneficiaries' meeting the requirement for Medicare coverage of a SNF stay. In establishing the 3-day hospital stay requirement for access to Medicare SNF coverage, Congress intended in substantial part to better assure that the SNF post-hospital benefit would be limited to beneficiaries who truly required a hospital level of care. But beneficiaries with the same hospital level of acuity are increasingly being treated in part in other settings. Thus, as CMS is aware, hospital lengths of stay have been substantially reduced at both the back end (through earlier discharge) and at the front end (though more outpatient pre-op procedures and through observation days). As practices change but the rules don't, at a minimum beneficiaries' appropriate access to Medicare's post hospital SNF benefit is reduced. In the worst case, failure to adapt the rules to changing practices results in perverse effects on Medicare costs and beneficiaries' care as unnecessary hospital days may be used just to satisfy the 3-day requirement.

In addition, Medicare does not treat an observation day consistently. Today, an observation day followed by admittance to a hospital counts as an "inpatient day" for the hospital, but does not count as a hospital "inpatient day" towards beneficiaries' required three-day stay to qualify for the Medicare SNF benefit. In our view, this is grossly inequitable.

Dr. Mark B. McClellan Page 28 July 12, 2005

AAHSA recommends that CMS count an observation day followed by an inpatient hospital admission as an "inpatient hospital" day toward the three-day hospital stay requirement for Medicare coverage of a subsequent SNF stay.

AAHSA appreciates the opportunity to submit our views on this issue and the time and consideration you devote to the comment process.

Sincerely,

Barbara B. Manard, PhD.

Vice President, LTC Health Strategies



AMERICAN THERAPEUTIC RECREATION ASSOCIATION

Founded 1984

July 11, 2005

OFFICERS

Nancy McFarlane, CTRS President Portland VA Medical Center Portland, Oregon

Bryan P. McCormick, Ph.D., CTRS President Elect Indiana University Bloomington, Indiana

Missy Armstrong Beyeriin, M.S., CTRS Secretary Harborview Medical Center Seattle, Washington

Diane Baumann, M.S., CTRS Treasurer Wellstone Regional Hospital Jeffersonville, Indiana

MEMBERS AT LARGE

Sharon D. Ballard, M.Ed., CTRS National Institutes of Health Bethesda, Maryland

Rebecca Chilcote-McGrath, CTRS Gentiva Rehab Without Walls Scottsdale, Arizona

Benjamin R. Curti, M.S., TRS/CTRS Wake Forest University Baptist Medical Center Winston-Salem, North Carolina

Mary Ann Keogh Hoss, Ph.D., CTRS Eastern Washington University Spokane, Washington

Nancy Richeson, Ph.D., CTRS University of Southern Maine Portland, Maine

AD HOC MEMBERS

Kelly Parker, CTRS Chair, Chapter Affiliate Council Mena Medical Center Mena, Arkansas

EX-OFFICIO

Ann D. Huston, MPA, CTRS Executive Director Alexandria, Virginia

Peter Thomas Legislative Counsel Washington, D.C. Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1282-P P.O. Box 8016 Baltimore, MD 21244-8016 رور 12 ـ الله عر**33:** ك

Re: Comments to CMS-1282-P

Dear Dr. McClellan:

Thank you for the opportunity to comment on the proposed skilled nursing facility ("SNF") prospective payment system ("PPS") update for federal fiscal year 2006. I am writing on behalf of the American Therapeutic Recreation Association (ATRA) to request that the Centers for Medicare and Medicaid Services ("CMS") amend its SNF regulations to clarify that recreational therapy is a covered service in the SNF setting and that, because the costs of recreational therapy have been built into the SNF PPS, these services must be provided to patients when medically necessary.

ATRA is the largest, national membership organization representing the interests and needs of recreational therapists. Recreational therapists are health care providers who use recreational therapy interventions for improved functioning of individuals with illness or disabling conditions. Recreational therapy – when physician ordered, going beyond the general activity program and focusing on active treatment to restore, remediate or rehabilitate a patient – has been proven to achieve significant outcomes for senior adults.

Research has proven that recreational therapy can improve secondary symptoms associated with Alzheimer's Disease and dementia (agitation, mood, depression, falls and behaviors); improve physical health, degenerative disorders and reduction in health risk (flexibility, strength, ambulation, range of motion, cardiovascular fitness, joint mobility, pain, weight management, posture, mobility, endurance, balance, coordination, bone strength, reliance on medications); improve cognitive functioning (alertness, attention span, memory, concentration, awareness, mood and behavior); and improve psychological health and social well-being (decreased loneliness, affiliation with others, social interaction, relaxation, coping, morale, self-concept, life satisfaction, competence, self-efficacy, depression, anxiety, stress and life quality). In addition, recreational therapy has been found to be a cost-effective option for providing rehabilitative services.



July 12, 2005

Mark B. McClellan, M.D., Ph.D Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1282-P P.O. Box 8016 Baltimore, MD 21244-8016 16:10 P.M.

Re: CMS-1282-P: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006; Proposed Rule

Dear Dr. McClellan:

The California Hospital Association (CHA) respectfully submits comments on the proposed rule for skilled-nursing facility (SNF) prospective payment system (PPS) refinements for Federal fiscal year (FY) 2006. CHA submits comments on behalf of its nearly 500 hospital and health system members, more than one-third of which operate hospital-based SNFs.

The proposed rule includes annual payment rate updates, proposed changes to the labor market definitions, proposed refinements to the resource utilization groups (RUGs), and other policy changes. While CHA supports some parts of the proposed rule namely, the annual payment updates and changes to the labor market definitions we do not support others.

CHA appreciates the Centers for Medicare & Medicaid Services' (CMS) attempt to address the fundamental flaw of the SNF PPS, which is a failure to adequately reimburse for non-therapy ancillary services. The proposed changes, however, make no significant difference in the reimbursement system as a practical matter. Thus, we cannot support the proposed refinements.

The Role of Hospital-Based SNFs

Hospital-based SNFs play a unique role in the continuum of care provided to Medicare patients. Hospital-based facilities care for patients who are moved out of the acute hospital because they are "stable," but who continue to need specialized care. These patients need access to the technology, treatment modalities and clinical resources found in hospitals.

Examples of the services these patients require include intravenous (IV) drug therapy, total parenteral nutrition, psychiatric evaluation, complex pain management, pharmaceutical consultation, hemodialysis, radiation, chemotherapy, complex discharge planning due to life-changing events, and complex social service intervention.

Freestanding facilities have consistently argued that their scope and depth of services are the same as those provided by hospital-based facilities. They are not. While similar services categories are available, they are provided in a significantly more limited scope.

Hospital-based facilities provide care to a distinctly different SNF population. This is reflected in the latest MedPAC data that shows freestanding SNFs have a positive operating margin under SNF PPS, while hospital-based SNFs have an incredible and unsustainable negative operating margin of 87 percent. A difference of this magnitude cannot simply be explained away as shifting of hospital overhead expenses. Rather, this differential is a testament to the fact that hospital-based SNFs provide a distinctly higher and more costly level of care than freestanding SNFs.

Congressional Mandate

Congress has mandated CMS to develop a refined payment system to more adequately reimburse SNFs for medically complex patients. It was nearly six years ago that the first mandate was imposed in the Balance Budget Refinement Act of 1999 (BBRA). In that act, Congress authorized a temporary add-on to certain RUGs until such time that a refined case mix classification system was implemented. Then, in the Benefits Improvement and Protection Act of 2000 (BIPA), Congress directed CMS to study alternative systems for categorizing Medicare SNFs patients according to their relative resource use.

CHA is disheartened that after all these years the best CMS can come up with is a proposal that maintains the status quo. It has been five years since CMS released any proposed changes for public comment. The BIPA study has never been released. In the meantime, hospital-based SNFs are left to operate in a financially untenable situation.

CHA strongly encourages CMS to continue working diligently on refining the RUG classification system. While Congress has recognized several problems in the system and made adjustments, it is critical to ensure that the RUG system adequately reflects the care needs of <u>all</u> patients, including those in hospital-based nursing facilities.

Proposed Refinements to the Case-Mix Classification System

CMS proposes to refine the SNF PPS by maintaining the general structure of the current payment system, while adding new payment categories to capture complex and costly patients who presently receive both extensive services and rehabilitation therapy. The proposed rule would create a new RUG category, Combined Rehabilitation and Extensive Care, to consist of nine new RUGs. The new category of RUGs would have the highest relative weights within the SNF PPS while other RUG weights would be decreased proportionally. CMS predicts that by removing the most clinically complex cases and accounting for them in a group of their own, both the new and remaining RUG categories would be more homogeneous. However, the payment system's predictive power would only marginally improve because of the new RUGs.

CMS found wide variability in non-therapy ancillary utilization within each RUG and across all 44 RUGs. Data show great variability in ancillary services utilized by different SNF residents grouped within the same RUG. CMS also found that patients classified into a less-intensive RUG may still receive significantly more expensive non-therapy ancillary services than patients in a more intensive RUG. The proposed rule recognizes that CMS cannot adequately explain

these discrepancies within and across RUGs, and that the addition of nine new RUGs does not eliminate or compensate for the discrepancies.

To address the high degree of variability in non-therapy ancillary utilization within and across the RUGs, CMS proposes an across-the-board increase to the nursing component of the case-mix weights for all 53 RUGs. The amount of the adjustment equates to approximately 3 percent of aggregate expenditures under the SNF PPS. CMS views this adjustment as a proxy for a non-therapy ancillary index, an element that was previously considered but found to add substantial complexity to the payment system. CMS is refraining from increasing the number of payment groups to capture different levels of non-therapy ancillary use, although other Medicare payment systems have significantly greater groups of payment categories than the currently proposed 53 RUGs.

CHA believes that the core problem with the current SNF PPS and perpetuated in this proposed rule is the failure of the existing payment system to fully reimburse SNFs for non-therapy ancillary services. On average, the higher acuity caseloads in hospital-based SNFs require more nursing time and non-therapy ancillary services than freestanding facilities. Therefore, underpayment of non-therapy ancillary services harms hospital-based SNFs to a greater degree. Yet these facilities must still bear the costs associated with maintaining the personnel and infrastructure needed to deliver these critical services, such as dialysis, respiratory therapy, IV therapy, laboratory and radiology.

Until a more targeted and effective remedy is available, hospital-based SNFs will continue to struggle with restrictions on their ability to serve the most medically fragile Medicare beneficiaries. More must be done in the interim to assist SNFs treating the sickest Medicare patients. CHA recommends that CMS implement a hospital-based SNF facility adjustment to support the medical infrastructure needed to care for beneficiaries with advanced skilled-nursing needs. The adjustment would recognize the costly personnel, equipment and other operational features that must be maintained to provide proper care for medically complex patients. This would provide needed relief until a comprehensive fix for underpayment of non-therapy ancillary services is available and implemented.

Outlier Pool

CHA encourages CMS to create an outlier pool equal to 2 percent to 3 percent of SNF payments. With new developments in medications and medical therapies, the need for an outlier is pressing. As has been noted in the past, some complex and high-acuity patients have difficulty finding a SNF that will admit them, and are forced to stay in an acute-care hospital unnecessarily. Given that all other PPSs in the Medicare program include an outlier policy, we believe that the SNF PPS should also.

Weighting

CMS should also consider weighting the per-diem payment through variable per-diem adjustments, as applied in the inpatient psychiatric facility PPS, which would pay a larger daily rate for the early days of a stay than the later days. This approach would be a good fit for the SNF PPS by acknowledging the higher costs incurred in the early days of a SNF stay. This would provide

an incentive to treat sicker, short-stay patients and help address the documented problem of limited access to care for these patients.

Qualifying Three-Day Inpatient Hospital Stay Requirement

In the original Medicare legislation, Congress imposed the requirement that a SNF stay would be covered only if it immediately followed a hospital stay of three or more days. It has been a long-standing policy interpretation to not count hospital observation time that immediately precedes an inpatient admission toward meeting the SNF admission requirement. However, previous comments have argued that the care furnished during observation may be indistinguishable from the inpatient care that follows formal admission, so the beneficiaries themselves often learn of the difference only after they are transferred to the SNF and fail to meet the SNF beneficiaries' prior hospital stay requirement. While CMS is not proposing a specific change, CMS invited comments on whether hospital observation days should be counted toward meeting the SNF beneficiaries' qualifying three-day hospital stay requirement.

In the inpatient setting, observation days count toward the inpatient length of stay if followed by a hospital admission. Patients often receive a full range of services during the observation phase. Therefore, there is no reason to disclude observation days from this count. As such, CHA supports a policy that counts observation days toward fulfillment of the SNF prior hospitalization requirement, as allowed under current statute.

Implementation of the Revised Labor Market Designations

For FY 2006, CMS proposes to adopt the revised labor market area definitions based on the Office of Management and Budget's Core-Based Statistical Area (CBSA) designations. Based on its analysis of the impact, CMS states that while some SNFs may experience decreases in their wage indexes, a significant number will benefit from the proposed change. As a result, CMS proposes to adopt the new CBSA designations and the resulting wage indices without a transition period and without a hold-harmless policy. CHA supports the new Metropolitan Statistical Areas designated in California. For payment purposes, the Micropolitan definition would add an additional layer of complexity, not to mention burden, to an already complex payment system. Thus, we agree with CMS' proposal not to adopt the use of Micropolitan areas.

Proposed Minimum Data Set Changes

CHA finds it ironic that at the same time CMS is proposing changes to RUGs to improve reimbursement for the medically complex, CMS is proposing changes to the minimum data set (MDS) that will do the exact opposite. The MDS modifications suggested in the proposed rule (i.e., the look-back period, grace days and anticipated therapy) would be very detrimental to facilities serving medically complex patients. Hospital-based SNFs would not have the wherewithal to bear these proposed MDS restrictions in combination with continued underpayment for non-therapy ancillary services. Any proposed changes should be presented with full analysis of their implications for patients and providers through formal rulemaking that allows for review and comment.

Below are CHA's comments in direct response to CMS' proposed MDS assessment item changes:

Eliminate 14-day look-back period with respect to P1a.

The 14-day look-back allows the SNF to provide continuity of medical treatment plans that were initially established in the acute-care setting; and enables the SNF to monitor for any continued side effects of the procedures done, and to monitor the clinical instability of patients post these procedures. Without the look back into the acute-care setting, the SNF will not be able to accurately capture the need for continued care.

Decrease or eliminate grace day period for five-day assessment.

The grace days associated with the five-day assessment allows the SNF to correctly capture the actual treatments given over a seven-day period of time without causing the patient the undo stress of submitting to therapy evaluations and treatments immediately upon admission to the SNF. If grace days are not allowed with the five-day assessment, we recommend that Section T of the MDS be programmed to identify rehab categories above the Rehab High category (i.e., Rehab Very High and Rehab Ultra High).

Decrease or eliminate grace day period for all assessments.

Grace days allow for the most appropriate capturing of the care rendered over a seven-day span of time. Without the benefit of grace days, it would be very difficult to accurately obtain the correct RUG score when looking at admission days/times, holidays and weekends.

Eliminate projection of anticipate therapy services during five-day assessment.

As identified in question two, either the grace days must remain or the ability of Section T (projection of anticipated therapy) must be expanded to capture the RUG scores higher than Rehab High. Without the ability to project minutes and days, it is impossible to obtain the minutes and days of therapy (in five days) that will be expended over a total of 14 days. In essence, all patients would have reduced access to care because facilities would not provide the same level of rehab if they would not be reimbursed for it.

Furthermore, the MDS items presented for discussion in the proposed rule should not be acted upon in a piecemeal fashion. CMS already has a process underway to update the current 2.0 version of the MDS, which has been the subject of ongoing discussions between CMS and national stakeholders in order to ensure that the pending revision effectively captures the primary concerns for CMS, providers and patients. All MDS changes should be conducted in a coordinated fashion with regard to the development of MDS 3.0 and a broader refinement of the SNF PPS.

CMS Should Share Data and Analyses

It would have been very helpful for providers and organizations, such as CHA, if the proposed rule would have been released along with the data and analyses used by CMS to develop the provisions in the proposal, especially for provisions that would restructure the RUGs. Specifically, the release of the full Urban Institute report would have been helpful, instead of a summary of the report. Also, a more detailed impact file with provider numbers would give providers and trade organizations the means of estimating impact of the proposed rule at the provider and national levels, which would in turn contribute to more robust feedback to CMS on how to strengthen the proposal. Without these data, stakeholders lack the key tools to assess the proposed rule and develop comprehensive, informed comments.

Concurrent Therapy

CHA supports the use of concurrent therapy. When used appropriately, it helps patients recover faster and return home sooner. Given the current shortage of therapists, concurrent therapy is an important to tool for providers. Elimination of it would detrimentally impact patients. We believe that the federal government already has the tools it needs to monitor and prevent inappropriate usage of concurrent therapy.

Dialysis

California hospitals are seeing an increasing number of patients who have complex medical needs and require dialysis, but are otherwise stable. These patients could be cared for by nursing facilities. Because of current Medicare coverage interpretations, however, these patients often remain in the hospital intensive care unit needlessly. As stated in CHA's letter to CMS dated May 3, 2005, on the proposed rule regarding conditions for coverage of end-stage renal disease facilities, we urge CMS to make it financially feasible for nursing facility patients to receive dialysis at the bedside from a dialysis facility or a SNF.

Thank you for the opportunity to provide comments on this proposed rule. If you have any questions or would like to discuss our comments, please contact Margot Holloway at (202) 488-4688 or mholloway@calhealth.org, or Judy Citko at (916) 552-7573 or jcitko@calhealth.org

Sincerely,

Margot Holloway

Vice President, Federal Regulatory Affairs

Mayot Blj Husway

Judy Citko

Vice President, Continuing Care Services

MH/JC:az

OBER KALER

Ober, Kaler, Grimes & Shriver Attorneys at Law

12C East Baltimore Street Baltimore, MD 21202-1643 410-685-1120/ Fax 410-547-0699 www.ober.com Howard L. Sollins hlsollins@ober.com 410-347-7369

Offices in Maryland Washington, D.C. Virginia

July 12, 2005

JUL 12 2005

Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Room 445-G, Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20201

http://www.cms.hhs.gov/regulations/ecomments

Attn: Mr. William Ullman

Re: SNF Certifications and Recertifications Performed by Nurse Practitioners and Clinical Nurse Specialists: 70 Fed. Reg. 29082

Dear Mr. Ullman:

On behalf of the National Conference of Gerontological Nurse Practitioners ("NCGNP") we are commenting on the above-referenced portion of the May 19, 2005 proposed changes to Medicare regulations governing the certification and recertification of Medicare beneficiaries for skilled care by nurse practitioners ("NPs") and clinical nurse specialists (the "Proposed Regulation"). NCGNP is the principal organization devoted to representing gerontological nurse practitioners practicing in a variety of settings, including skilled nursing facilities ("SNFs").

NCGNP is concerned that the Proposed Regulation, although characterized as a clarification, is, in fact, a major departure from established policy governing the role of nurse practitioners providing essential services in SNFs. NPs not only provide professional services covered by Part B, but they are also contracted by SNFs to provide additional services, such as quality assurance, training and teaching and similar support. While NPs do not serve as SNF medical directors, they may provide

additional support to medical directors. Where the SNF does not employ the NP, the SNF may enter into a contractual arrangement, either with the NP individually, or with another entity employing the NP, such as a local medical group, hospital or other entity. This is often done on an independent contractor basis, rather than as an employee. Such NPs may also be well-qualified to determine that an individual resident should be certified or re-certified as requiring skilled care for which Part A reimbursement is available, in the same manner as NPs not otherwise providing such other services.

The Proposed Regulation is grounded on the baseless assumption that NPs providing services to the SNF, the cost of which is included in the SNF's Part A rate, are inherently incapable of making an unbiased clinical judgment concerning the resident's need for skilled services for which Part A reimbursement is available, simply because they provide certain additional services to the SNF that are included in the SNF's Part A rate. No similar restriction applies to independently contracting physicians rendering services to SNFs where they provide services that are likewise included in the Part A SNF rate, such as when an outside physician services as medical director.

Federal law prohibits NPs directly or indirectly employed by the SNF from making such a certification or recertification of Part A eligibility. We appreciate the acknowledgment by the Centers for Medicare & Medicaid Services ("CMS"), on page 29082 of the proposed regulation, that Congress' restriction on the ability of NPs directly or indirectly employed by a SNF to certify a beneficiary's skilled status is "very restrictive." We acknowledge that, while we disagree with this underlying employment-based restriction, our remedy rests with Congress.

However, we urge CMS not to adopt a more rigorous and even more restrictive definition of "indirect" employment so as to include NP relationships that are beyond the scope of the statute. Employees are distinguished from independent contractors. Independent contractors, by definition, are individuals in a position to determine the manner and means by which they perform their functions for another party. The common law test of "employment" under 20 C.F.R., Sections 404.1005, 404.1007 and 404.1009 provide a well-known and widely understood definition of "employment." Independent contractors are, by definition, independent in the manner and means by which they provide services, notwithstanding that they are paid for services. The Proposed Regulation ignores this distinction, in logic and law. While the Proposed Regulation recites that CMS has periodically been asked to interpret this regulation, no history of conflict of interest, overutilization, reversals of eligibility determinations or

otherwise has been cited. A NP who is otherwise attending patients and is familiar with the SNF, its residents and operations, might contract to provide a particular service, such as an analysis of ways care could be improved in a particular area, but under the Proposed Regulation this could only be done by relinquishing an otherwise permitted ability to certify the need for Part A benefits for the residents with whom the NP is very familiar as a practitioner.

The Proposed Regulation offers only the unsupported allegation that "an SNF that has an NP or CNS perform [] general nursing services is essentially using the NP or CNS in the same manner as it would an employee..." The logic is inherently circular, i.e. NPs providing independent contractor nursing services, such as quality assurance, teaching or similar support are included within the definition of an employee because they are being used like an employee. Independent contractors may provide services an employee may perform, whether directly employed by the SNF or indirectly employed by the SNF (as may exist where the NP is employed by a corporate affiliate of the SNF. However, that overlap in function does not mean the SNF has the same control. In fact, the contrary is true, i.e. if a NP providing services to a SNF is controlled in a manner that would ensure the NP's activities are controlled by the SNF, the NP would not be an independent contractor. If the NP can qualify as an independent contractor because of the NP's independence in the performance of the NP's duties, there is likewise no conflict of interest. The existence of a financial relationship does not create an inherent conflict, where the NP owes no duty to the SNF or any affiliate of the SNF other than to provide the contracted services.

Where Congress intends for a law to extend to independent contractors, it so states. See, Section 1842(b)(6(C) of the Social Security Act (stating expressly where an independent contractor relationship is intended to fall within an "employment" relationship). Also, CMS draws a distinction between independent contractors and individuals who function as "leased employees." See, e.g., 42 C.F.R., Section 410.26(a)(3) and (4). Yet, the Proposed Regulation ignores this well-recognized distinction.

Moreover, many NPs providing services to a SNF are not paid by the SNF. Rather, they are employed by a medical practice, hospital or other entity that provides the NP's services to the SNF. Thus, the financial benefit runs to the NP's employer who contracts with the SNF to provide the NP for both medical services and other support, not the NP. Where that is the case, the NP's primary employment-related duty is to the

NP's employer, not the SNF contracting for the NP's services. There is no financial incentive upon which even a suggestion of conflict could be based.

CMS solicits, in the Proposed Regulation, comments on the effect of this "clarification." One effect will be to harm efforts to improve the quality of care in SNFs. One effect of the Proposed Regulation, if adopted, would be to dissuade SNFs from using NPs to provide support that enhances the quality of care, if in doing so the NP would be disqualified from performing certifications and recertifications of skilled status. NPs provide an important function in being able to support the activities of medical directors, perform quality assurance and staff and resident teaching. CMS' Action Plan for Further Improvement of Nursing Home Quality, issued in December, 2004 (p. 7) recognizes the role NPs and other Advanced Practitioners play in such quality improvement efforts. Moreover, CMS is in the process of finalizing major changes to F 501, the F Tag governing medical director services. Those new survey guidelines will substantially increase the expectations for the involvement and performance of medical directors in SNFs and NFs. Physicians who provide medical director services often benefit from support by NPs. Where a physician signs a medical director contract with a SNF that also includes corollary assistance from an NP, the Proposed Regulation would disqualify the NP but not the medical director from certifying and recertifying the residents for Part A benefits, even though they are equally independent.

CMS has ample tools it uses to ensure there are proper determinations of eligibility for coverage. The Program Integrity Manual, under Section 4.2.1, details grounds for action, even against employees. These protections and sanctions are available remedies to ensure proper certifications and recertifications. We also note that NPs are permitted to order reimbursable services, under Section 5.1.1.5 irrespective of any independent contractor relationship. The risks are no higher when it comes to certifying a beneficiary as eligible for skilled care, than they are for an NP to determine that a resident needs a Part B-reimbursable service. We respectfully suggest that the question upon which CMS should focus is whether beneficiaries are receiving timely and accurate determinations of skilled status and eligibility for Medicare benefits. Absent any substantive basis for a determination that either independently contracted NPs or NPs employed by outside entities that, in turn, provide them under contract to the SNF, are making determinations reflecting the influence a conflict of interest the Proposed Regulation is, at best, baseless and, at worst, wrongly suggestive that NPs providing contracted services have a moral compass that is weaker than physicians

providing medical care to residents and also providing support that is covered under a Part A rate. Such a conclusion is unfair and unwarranted.

In summary, we appreciate that CMS must implement the statutory restriction on permitting indirectly employed NPs from certifying and recertifying beneficiaries for skilled care. However, there is no factual, statutory, or policy support for determining that independent contracting NPs or NPs who are contracted through other entities to provide beneficial services to SNFs are in a conflict of interest position. We urge that this Proposed Regulation not be adopted.

Sincerely,

Howard L. Sollins

26-14



Providence | Health System

July 12, 2005

Honorable Mark B. McClellan, M.D., Ph.D. Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006 – Proposed Rule CMS -1282-P

Dear Dr. McClellan:

On behalf of the Providence Health System, I want to thank you for the opportunity to provide our comments on the changes proposed by Centers for Medicare and Medicaid Services (CMS) to the Medicare Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities. CMS published these changes as part of its Notice of Proposed Rule Making in the Federal Register on May 19, 2005. The Providence Health System is a faith-based, non-profit health system that operates 19 skilled nursing facilities (SNFs) with 1,741 beds in Washington State, Oregon, California and Alaska, along with hospitals, physician groups, home health agencies, assisted living, senior housing, PACE programs, and a health plan. In 2005 the Providence Health System provided 504,354 patient days of care in our skilled and nursing facility operations. As a provider operating both hospital-based and freestanding facilities, the Medicare SNF Prospective Payment System (PPS) paid for many of these services.

Providence is pleased to provide its comments and recommendations to CMS on the following issues contained in the proposed rule.

- Refinements to the case-mix classification system including the following suggested revisions to the MDS Manual:
 - □ Modify the 14-day "look-back" provision that governs the completion of Section P(1)(a) to only allow inclusion of those special care treatments and programs furnished to the resident since admission or re-admission to the SNF:
 - □ Decrease or eliminate the "grace day" periods associated with all PPS-related MDS assessments; and

- □ Eliminate the ability to project anticipated therapy service utilization as part of the initial 5-day MDS assessment required for PPS.
- Resource Utilization Groups (RUGS) for payment purposes. It needs to be stated and understood that Providence's position with respect to this particular proposal cannot be separated from its position regarding the suggested revisions to the MDS Manual: The decision to create new payment categories is inextricably linked to the data definitions and the accompanying data collection methodology used to assign a patient to a particular RUGS category. Thus, in offering its support of the nine new categories that result from recognizing the care needs and resource utilization of patients with Rehabilitation and Extensive Service needs, Providence is specifically conditioning its approval to an interrelated decision to retain the current MDS manual provisions. Simply stated, if some or all of the suggested revisions to the MDS Manual were accepted then the proposal to add nine new RUGS categories cannot be thoughtfully analyzed and in the absence of that analysis would need to be rejected.

Beyond this initial caveat, Providence offers its perspective concerning the adequacy of the adjustment proposed by CMS to recognize the remaining large and unexplained variation in non-therapy ancillary use and cost. Additionally, in response to the agency's invitation to comment on the economic impact of the resulting payment changes, Providence is further requesting that CMS make an adjustment to account for the higher non-labor costs of SNFs in Alaska.

- The regulatory approach and timeline for implementation of the proposed changes to the payment system in light of the attendant provider responsibilities.
- Revisions to the composition of SNF labor markets for PPS and associated data sources used to create the wage indices that adjust the labor-related portion of the rate.
- Expansion of the presumption for level-of-care eligibility determinations to include the nine additional RUGS categories proposed by CMS.
- Possible conditions on the use of "concurrent therapy" as a treatment approach for patients needing therapy services in order to ensure that it is clinically justified and appropriately utilized.
- Proposed expansion of the prohibition on the use of nurse practitioners and clinical nurse specialists for certifications and re-certifications to include situations where there is an "indirect" employment relationship with the skilled nursing facility.

- Overall comments concerning the general regulatory direction set forth by CMS with respect to enhancing quality in the postacute continuum through appropriate incentives and coordinated case mix systems.
- Inclusion of "Observation Days" as that term is defined in the Hospital Outpatient Prospective Payment System (HOPPS) to determine whether a patient has met the qualifying three-day inpatient hospital stay requirement for post-hospital extended care benefits.
- Suggested additions to the list of services that are excluded from the Part B
 Consolidated Billing requirements for patients whose stay is paid for under
 Part A.

In offering these observations and comments, Providence has been greatly aided by the informed perspectives of its clinical and administrative leaders who work each day to provide high-quality skilled nursing facility care.

"Proposed Refinements to the Case-Mix Classification System"

In its preamble to the changes proposed in this notice, CMS addresses the distinct but clearly related issues of how the needs of patients are assessed and subsequently assigned a patient to a payment category using these same data elements. In this section of its comments Providence addresses the assessment-related issues. The section that immediately follows will then speak to the use of this data for payment-related purposes.

These MDS policies and criteria (look-back period, grace days and anticipated therapy) were integrally linked to the staff time studies that were used to develop the RUGS categories and weights. Any changes in these policies should only be implemented if and when a completely new case mix classification system is developed and/or new staff time studies are undertaken. With this overriding point in mind, Providence would now like to direct its attention to reasons specific to each proposal that we believe provide an additional basis for not proceeding with any of the MDS-related policy changes.

• Modify the 14-day "look-back" provision that governs the completion of Section P(1)(a) to <u>only</u> allow inclusion of those special care treatments and programs furnished to the resident since admission or re-admission to the SNF.

Comment: Providence believes strongly that the provisions of the MDS Manual that permit use of a 14-day "look-back" period to include hospital services provided prior to the most current admission to the SNF should be retained. It needs to be remembered that the use of the MDS as an assessment and careplanning tool predates its application as a basis for assigning patients to specific RUGS categories. As the three following scenarios suggest, there are valid clinical reasons for retaining the current instructions in the MDS Manual.

Scenario 1: A patient is admitted to hospital following a fall with subsequent hip fracture. They have also been diagnosed with prostate cancer and receive leuprolide injections every three months. The morning prior to discharge from the hospital the patient receives a leuprolide injection. Capturing this information utilizing the 14-day look-back for item P(1)(a)(a) [Chemotherapy] guides the nurse in identifying this treatment and ensuring that appropriate follow through occurs via the subsequent Resident Assessment Instrument process. These services provided after admission to the SNF would include monitoring the patient for side effects of the chemotherapy and ensuring that appropriate laboratory tests are scheduled.

Scenario 2: A patient is admitted to hospital with an infection that is only susceptible to treatment with vancomycin. The medication is administered intravenously and the last dose is administered the day of discharge from the hospital. Capturing this information via the 14-day look-back for item P(1)(a)(c) [IV Medication] assists the nurse in identifying this treatment and ensuring that the patient is monitored for decreased renal function, cellulitis at the IV insertion site, and any further infection complications.

Scenario 3: A patient admitted to hospital with exacerbation of COPD. During the hospital stay, the patient requires the use of intermittent oxygen therapy. Capturing this information via the 14-day look-back for item P(1)(a)(g) [Oxygen Therapy] enables the nurse to identify this treatment and ensures the patient is closely monitored for blood oxygen saturation levels on a routine basis. The nurse can plan education sessions with the patient and his/her family on oxygen use and safety during the patient's stay in the nursing home and make arrangements to ensure the appropriate supplies are in place upon discharge.

All of these scenarios illustrate the RAI-mandated process of gathering information and then using this information to complete the assessment, identify areas for further assessment, and coordinate the patient's plan of care. Many medical procedures and treatments in section P(1)(a) have long-range impact on patients following their hospital stay and after their admission to the SNF: Items in P(1)(a) impact patient care-regardless of whether or not the service occurred in the nursing facility. To eliminate the 14-day look-back period would have a detrimental affect on the RAI process and have a potential negative impact on patient outcomes. Furthermore, each of these examples illustrates the point that even though the identified service using the 14-day look-back period was provided in the hospital setting, they impact subsequent nursing time and resource use in the SNF.

Furthermore, there appears to be no policy rationale for this change beyond the discussion in the preamble that speaks to the potential for cost savings.

Decrease or eliminate the "grace day" periods associated with all PPS-related MDS assessments.

Comment: Beyond Providence's general comments with respect to all of these proposed MDS changes, we believe there are two key issues specific to this proposal that warrant its dismissal. First, with respect to the initial five-day assessment, the grace period is an appropriate tool to allow a facility to more accurately reflect the needs of its patients (and requisite resources and payment) for the first 14 days of the patient's stay. This position was also affirmed by CMS. In the Final SNF PPS Rule CMS offered an explanation for the appropriate use of grace days: On page 41657 of the Federal Register published on July 30, 1999 CMS stated,

"Unlike the routine use of grace days described above, we do expect that many beneficiaries who classify into the rehabilitation category will have 5-day assessment reference dates that fall on grace days. There are many cases in which the beneficiary is not physically able to begin therapy services until he or she has been in the facility for a few days. Thus, for a beneficiary who does not begin receiving rehabilitation therapy until the fifth, sixth or seventh day of his or her SNF stay, the assessment reference date may be set for one of the grace days in order to capture an adequate number of days and minutes in Section P of the current version of the MDS to qualify the resident for classification into one of the rehabilitation therapy RUG-III groups.

Another reason for the provision of three grace days for the 5-day assessment was to make it possible for beneficiaries to classify into the two highest RUG-III rehabilitation sub categories. Classification into the Ultra High and Very High Rehabilitation subcategories is not possible unless the beneficiary receives the sub-category's minimum level of services during the first seven days of the stay.

We also intended to minimize the incentive for facilities to provide too high a level of rehabilitation therapy to newly admitted beneficiaries. Having these extra few days allows time for those beneficiaries who need it, to stabilize from the acute care setting and be prepared for the beginning of rehabilitation in the SNF."

Beyond this use of grace days for the initial five-day assessment, grace days also permit a facility to coordinate the completion of an OBRA-related assessment with one required for PPS purposes. The following scenario illustrates this point.

Scenario: A patient is admitted on July 1, 2005 that coincides with the first day of their Medicare Part A stay. The facility sets the Assessment Reference Date (A3a) for both the 5-day PPS and the OBRA-mandated admission assessments for July 5, 2005. The MDS Manual requires that the MDS must be completed (R2b date) by July 14th in order to meet the OBRA requirement for the Admission MDS.

PPS Rules allow the A3a date for the 90-day assessment to be from 80-89 days with a grace period of up to day 94. These timeframes equate to September 18th through the 27th with a grace period extension out to October 2nd. However, OBRA requires the completion (R2b) of the Quarterly assessment to be not more than 92 days from the R2b date of the previous (Admission) OBRA assessment: This means the OBRA 90-day assessment has to be completed (R2b) no later than October 13th. By using the "grace" days, we are able to stay as close to the OBRA quarterly schedule as possible and avoid more than one assessment. Simply put, we would set the A3a date for both the 90-day PPS and Quarterly OBRA assessment to be either September 29th or 30th (day 91 or 92) and complete (R2b) the assessment no later than October 13th.

CMS found this use of grace days as a means of coordinating assessments to be appropriate. In the Final Rule referenced previously, CMS stated,

"(Use of grace days) are also acceptable, and for some residents may actually be more appropriate; for example, to allow maximum flexibility for nurses to determine when to set the assessment reference date for the beneficiary's MDS, and thereby lessen the burden of the increased frequency of assessments that accompanied the PPS."

Clearly then, grace days are an important mechanism for care planning and coordination and a means to capture the clinical needs of the patient for RUGS assignment. Consequently, suggested MDS changes to eliminate or decrease the use of grace days should not be adopted.

• Eliminate the ability to project anticipated therapy service utilization as part of the initial 5-day MDS assessment required for PPS

Comment: In the case of a Medicare five-day assessment, the clinician uses MDS Section T to capture minutes of therapy that are *anticipated* for the beneficiary during the first two weeks of the nursing home stay. Absent this provision, it would be impossible for the beneficiary to classify into a category greater than the high RUG-III rehabilitation group for the first 14 days of their covered Part A stay. This policy consequence would come at a time when a number of MEDPAC reports have suggested that there are significant financial disincentives for a patient to be assigned to those two categories. CMS should not adopt a policy that has the albeit unintended consequence of potentially creating another access barrier for these beneficiaries.

"Case-Mix Adjustment and Other Clinical Issues"

As noted in our overall introduction to these comments, Providence cannot evaluate and therefore cannot support any changes to the current RUGS categories if the suggested MDS Manual changes were to be adopted. Quite frankly, it is our hypothesis that the

practical effect of these MDS Manual changes would be to "downcode" many of the beneficiaries that CMS is proposing to assist through the creation of the nine new RUGS categories and the adjustment to the nursing weights. However, assuming that those changes will not be adopted for the reasons enumerated above, Providence would now like to direct its comments to this area. Two fundamental policy questions are essentially in play: First, "is the proposed method of distributing payments among the proposed case-mix categories more equitable than under the current system" and second, "does the proposed aggregate level of funding to be distributed appropriately account for case mix." This questions are interrelated and they intersect at the point a beneficiary is seeking care and a provider is attempting to meet their needs. If both questions cannot be answered in the affirmative then adapting the principles of the Hippocratic Oath CMS should first "do no harm" and changes should not be made. Our analysis is complicated by the fact that the so-called BBRA and BIPA add-ons expire once case mix refinements are in place. CMS is proposing to make such a finding with this proposal. It is in this context that Providence offers the following comments.

 Is the proposed method of distributing payments among the proposed case-mix categories more equitable than under the current system: The case for the nine new case mix categories.

As we reviewed the proposed changes we were appreciate of the work that had been done and mindful of the work still to be done. And yet, as our clinicians looked at the care needs and resource uses of our patients – especially the use of non-therapy ancillary services - it became clear that the current classification of patients with both Extensive Services and Rehabilitation needs was inadequate. Creating the nine new RUGS categories and placing these patient groupings at the "top" of the hierarchy increased the predictability of the model. While we can bemoan the relative low r-squared, we - and the patients we serve - have lived with the current system's inadequacies for over seven years. Quite frankly, we are reminded that "perfect is often the enemy of good" when it comes to policy solutions: waiting for a possibly higher predictive value in the future should not be the basis for delaying needed improvements now. Furthermore, as we consider all of the methodological issues to even establish a proxy for non-therapy ancillary costs to say nothing of the effort to assure that the claims accurately reflect such use is no small task. Needed improvements today should outweigh the potential promise of future benefits, if they can be realized at all. For these reasons, Providence supports the inclusion of nine new RUGS categories described in the proposed rule. However, as noted above, there is another issue to be considered.

 Does the proposed aggregate level of funding to be distributed appropriately account for case mix: The question of economic impact.

Quite frankly, Providence was gratified by the fact that agency asked for comments on the proposed weighting adjustment being proposed for the nursing weights and an overall assessment of economic impact resulting from these changes. Providence was admittedly surprised that the agency chose to use its discretionary authority to partially offset the effects of the elimination of "temporary add-ons" authorized by BBRA and BIPA. We applaud the agency for its wisdom in this regard but believe that an additional adjustment is warranted given the significant variation in non-therapy ancillary use within and among case-mix groupings that remains. It would also appear to Providence that such an adjustment is warranted given the fact that cost of non-therapy ancillary services – the very issue needing to be addressed – as clearly been increasing at a faster rate than the market basket adjustments. More work needs to be done and the re-distributional effects notwithstanding this adjustment are potentially great. For these reasons **Providence would urge CMS** to use its discretionary authority make an even-larger adjustment to offset the entire effect of the \$1.2 billion "withdrawal" from the aggregate funding pool and provide a full market basket adjustment. Such an action would be consistent with our guiding principle of "do no harm" and given CMS discretionary authority to make adjustments under §1888(e)(4)(G)(i).

 Finally, given the invitation by CMS to speak to the economic impact of these changes, Providence would stress the need for the agency to make appropriate adjustments to reflect the higher non-labor costs of skilled nursing facilities in Alaska.

Section 106 of the Balanced Budget Refinement Act of 1999 (Public Law 106-479) authorized a MEDPAC study to determine whether skilled facilities in Alaska and Hawaii needed an additional payment adjustment to take into account their special circumstances. MEDPAC contracted with the Lewin Group for this analysis and a report was presented in April of 2001 that documented the following conclusions:

- □ Alaska has the highest cost per case of any state for hospital care;
- Cost-of-living indexes showed that Alaska was among the most expensive places in the United States. Of special note was the fact that on several measures (food costs, utilities, and construction) Alaska ranks at or near the top of expense categories.

MEDPAC voted 11-0 to recommend reinstatement of the non-labor adjustment factor: Consequently, Providence would strongly urge CMS to adopt this provision, much in the same manner the agency adopted a similar provision when considering the proposed Inpatient Psychiatric Prospective Payment System and in adopting other longstanding payment policies.

"IMPLEMENTATION ISSUES"

In this notice CMS proposes to implement the 3% market basket adjustment and the changes to the new labor markets and wage indices as of October 1st. The new RUGS-53 system would become effective as of January 1st, 2006 at which time the temporary

BBRA and BIPA-related add-ons would expire and an adjustment to the nursing weights would be implemented.

<u>Comment:</u> Providence supports this approach and timeline. In our past comments we had urged the agency to allow enough time for software installation and staff and provider training. We have consulted with our vendors and the changes can be quickly made assuming the official RUGS-53 GROUPER logic is published within a short period of time following publication of the final rule.

"PROPOSED REVSIONS TO THE SNF PPS LABOR MARKET AREAS"

CMS is proposing to adopt the revised labor market are designations based upon the Core-Based Statistical Areas (CBSAs) developed by the Office of Management and Budget. While the discussion in the regulatory preamble lays out a number of options for efficient implementation of the proposed CBSA designation, the agency is proposing not to adopt a transition period for implementation.

<u>Comments:</u> Providence supports the use of Core Based Statistical Areas as a basis for delineating urban and rural areas for purposes of applying the appropriate wage index. Furthermore, because any transition period would be implemented in a budget-neutral fashion, the number of affected entities is small, and the actual impact is slight, we concur with the judgment of CMS that a transition period is unnecessary.

"WAGE INDEX DATA"

CMS proposes to use hospital wage data as a basis for calculating the appropriate wage index that is then applied to the labor-related portion of the standardized rate. CMS is proposing this approach even though the statute suggests SNF wage data should be collected and used.

Comments: Consistent with our past comments on this issue, Providence supports the continued use of hospital wage data as a basis for establishing the SNF wage indices. The SNF wage data that was previously collected was fraught with errors and in need of additional audit work. Until that data has a high degree of credibility it should not be used for such an important purpose. Furthermore, it has been our experience that the SNF labor market does not act independently of the larger hospital market for the services of labor.

"PRESUMPTIVE ELIGIBILITY FOR A SNF LEVEL OF CARE"

As part of its annual update CMS publishes a list of RUGS categories that have presumptive eligibility from a level of care standpoint (assuming all other program

criteria are met). In this proposal CMS proposes to expand this presumption of level-of-care eligibility to include the nine additional RUGS categories proposed by CMS.

<u>Comments:</u> Providence supports the addition of the nine new RUGS categories to the 26 already used for this purpose.

"CONCURRENT THERAPY"

CMS acknowledges in the preamble that concurrent therapy can have a legitimate place in the spectrum of care options available for therapists treating Medicare beneficiaries, as long as its use is driven by valid clinical considerations. However, CMS is troubled by reports that other, purportedly non-clinical factors are influencing and impacting how therapists are using this practice and is seeking comments.

Comments: We concur with the assessment that concurrent therapy is a legitimate delivery option: Indeed, it has been our experience that concurrent therapy may often be the best approach given the individualized needs of the patient. To the extent that some therapists may be driven by criteria other than those motivated by clinical needs of the patient then we would expect to see a difference between what is being provided, the actual outcomes being achieved by the patient, and the therapy care plan. To the extent that these outcomes are observed then we believe CMS already has the regulatory prerogative to intervene.

"SNF Certifications and Recertifications Performed by Nurse Practitioners and Clinical Nurse Specialists"

CMS is proposing to revise its regulations found at 42 CFR §424.20(e) to further expand the prohibition on the use of nurse practitioners and clinical nurse specialists for SNF certifications and recertifications to include situations where there is an "indirect" employment relationship with the skilled nursing facility. Even in the absence of a direct employment relationship, an indirect employment relationship would presume to exist where a SNF is essentially utilizing the nurse practitioner or clinical nurse specialist to perform general nursing tasks in the same manner that it would an employee. In an effort to define the reach of this change the proposed regulation would utilize existing language at 42 CFR § 409.21 to define nursing tasks.

Comment: Providence strongly supports the greater involvement of these professionals in the delivery of clinical services to SNF and NF residents. However, the language at 42 CFR § 409.21 is too broad and fails to provide the necessary clarification to what is by definition a less-than-direct relationship. Providence believes that the proper issue is not what are the specific tasks being performed but rather who is providing the direction and supervision of the nurse practitioner or the clinical nurse specialist. To the extent it is the SNF then that clearly an indirect employment relationship exists. To the extent that these individuals are working under the direction and supervision of the physician as

encompassed by the definition of "collaboration" found in 42 CFR 424.20(e)(2)(i) then no indirect employment relationship should be presumed.

"Proposed Refinements to the Case-Mix Classification System - Quality"

In the text accompanying the proposed regulations CMS makes some compelling arguments about the need to build quality incentives into the reimbursement system in addition to modifying the current reimbursement framework for the entire continuum of postacute services. The discussion was far-reaching, provocative, and replete with implications for providers and beneficiaries alike. While it is beyond the scope of this comment period to draft a comprehensive approach at this time, Providence would encourage CMS to engage in a regular and continuing dialogue as to what is its research agenda that underlies these approaches. To use but one example: the implications of using a standardized assessment tool in an effort to make the system more patient-centric are profound to say nothing of the effort required to reach agreement. This argument is not to discourage these efforts but rather a plea for CMS and its research partners to engage in more dialogue with the provider and beneficiary community on these issues.

"Observation Days"

In an extremely progressive proposal that recognizes the changing practice patterns of acute care hospitals and their unintended consequences for beneficiaries needing SNF care, CMS is proposing to include "Observation Days" - as that term is defined in the Hospital Outpatient Prospective Payment System (HOPPS) - to determine whether a patient has met the qualifying three-day inpatient hospital stay requirement for post-hospital extended care benefits.

<u>Comments:</u> Providence has seen this practice repeatedly cause a beneficiary to fail to meet the three-day prior hospitalization requirement even though the patient has been continuously served at the hospital over the course of three consecutive midnights but not in a formal inpatient status. We applaud the agency for its efforts in this regard and for developing the appropriate rationale to support this change. **Providence heartily endorses this proposal.**

"CONSOLIDATED BILLING"

CMS is explicitly soliciting proposals as to additional HCPCS codes that should be added to the list of services that are excluded from the Part B Consolidated Billing requirements for patients whose stay is paid for under Part A.

<u>Comments:</u> We would ask that the following codes and services be considered by the agency for possible additions to this list:

- Radiation therapy: 77414, 77427, 77336
- MRI: 70553, 72141, 72195, 73221

• Swallowing function exam: 74230

• Ultrasound: 76872

- Lupron (leuprolide acetate) a chemotherapy agent given for prostate cancer
- Prosthetic devices: "Left Hip Abductor Brace"
- Complex pharyngeal speech evaluation: 70371

Bone and Joint Imaging: 78306

Additionally, in the same manner in which CMS is wisely proposing to use its authority to adjust its 40-year old, three-day prior hospitalization standard partly in recognition of changing hospital practices, we would encourage CMS to revisit the issue of determining when certain services are clearly beyond the scope of a SNF care plan. Providence SNFs are being deluged with request for Part B payments that we believe are typically hospital services but for the fact they are being provided in a hospital joint venture that is not provider-based or in another freestanding arrangement, most often in the physician's office. In offering this comment Providence is not proposing that the SNF could not act as an aggregator for these bills and act as a single agent for Part B billing. However, absent some flexibility on this issue the practical effect of the current policy is to place SNFs solely liable for payment of some very high-cost and infrequent services that are clearly beyond its care plan. Some examples that are particularly noteworthy include:

- MRI (76394) and CT scans performed in the only (freestanding) imaging site in the community;
- Radiation therapy similarly performed in a physician's clinic/ambulatory care center;
- EPO 634, 635 /Aranesp 636 provided to non-dialysis patients, CA patients for whom it is clinically appropriate and ordered;
- Specialized bariatric equipment

Again, thank you again for the opportunity to comment on these proposed changes. If you have any questions, please contact Chuck Hawley, Vice President of Government Affairs, at (206) 464-4237 or via e-mail at chuck.hawley@providence.org.

Sincerely,

John Koster, M.D. President/CEO

Providence Health System

John Kostu mo



27-H

July 11, 2005

HAND-DELIVERED

Mark B. McClellan, MD, PhD Administrator Centers for Medicare & Medicaid Services Room 445-G Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20201

Re: CMS-1282-P

Proposed Rule – Prospective Payment System for Skilled Nursing Facilities for FY 2006 Federal Register, May 19, 2005, pp. 29070-29162

Dear Dr. McClellan:

The American Speech-Language-Hearing Association (ASHA) is the professional and scientific association representing over 118,000 speech-language pathologists, audiologists and speech-language and hearing scientists qualified to meet the needs of the estimated 49 million (or 1 in 6) children and adults in the United States with communications disorders. We appreciate the opportunity to comment on the proposed rule affecting skilled nursing facilities. Our comments relate to the following topics:

- Impact of the proposed 6.7% reduction in value of 14 current rehabilitation-intensive RUGs;
- Appropriateness of the three grace days allowance added to the resident's 5-day assessment period;
- Appropriateness of anticipated therapy projections;
- Designing Pay for Performance programs; and
- Concurrent therapy by speech-language pathologists.

Mark B. McClellan, MD, PhD July 11, 2005 Page 2 of 4

Reduction in value of 14 current rehabilitation-intensive Resource Utilization Groups

We believe that the 6.7% reduction in the payment amount for the rehabilitation Resource Utilization Groups (RUGs) will result in further reductions of speech-language pathology services rendered. We have presented concerns in prior SNF regulatory comments that the current payment structure encourages the provision of only the minimum number of therapy minutes per RUGS category, rather than the amount that the patient could best benefit from. The Medicare Payment Advisory Commission (MedPAC), in its June 2005 Report to Congress¹ cites a 2002 GAO report as well as studies published in 2003 and 2004 that found evidence that SNFs may have responded to therapy-related payment incentives such as providing minutes of therapy at the low end of the range for a given RUG category. The proposed lower payment for rehabilitation RUGs will only exacerbate this problem by increasing the incentive to reduce costs by decreasing therapy services.

Another restrictive technique by which SNF administrators have reduced rehabilitation expenses is by discouraging the performance of fluoroscopic and endoscopic assessments of swallowing. The 6.7% reduction, specific to rehabilitation RUGs payments, will motivate administrators to increase this type of behavior and will translate into lower overall quality of care. The videofluoroscopic swallow studies are a very visible drain on the SNF's financial resources and are even more expensive with the addition of ambulance costs. As we have stated in prior regulatory comments, CMS should partner with the private sector in persuading Congress to exempt videofluoroscopic swallow studies (CPT 92611 paired with CPT 74230) from the PPS per diem. In the meantime, we ask that CMS find a creative way to increase the payment amounts of the rehabilitation RUGs.

Proposed Refinements to the Case-Mix Classification System

Appropriateness of three grace days. CMS requests comments on the appropriateness of the current allowance of three grace days added to a SNF resident's 5-day assessment period. ASHA believes it is important to allow the grace days for the initial assessment period in order to more accurately estimate the amount of therapy required and maintain efficiency in staffing by not requiring rehabilitation staff to be on call for weekend assessments. In rural areas, weekend therapy coverage can be virtually impossible due to the lack of available staff. During the first day or two after admission, a speech-language pathologist may not be available or a resident may be disoriented or weak and not be able to participate in therapy. Also, activities other than therapy are the first priorities after admission, such as addressing the care needs of the patient (nursing assessment), medical concerns (pharmacy and medical treatments), and the provision of initial front line staff training. The grace days are especially important for residents who require higher levels of rehabilitation intensity; that is, it would be impossible to qualify some residents as Very High or Ultra High rehab without grace days.

¹ Medicare Payment Advisory Commission. Report to Congress: Issues in a Modernized Medicare Program (June 2005), p.124.

Reasons for the grace days, as presented in the past by CMS, appear reasonable:

Grace days may also be used to more fully capture therapy minutes... The use of grace days allows clinical flexibility in setting Assessment Reference Dates, and should be used sparingly. (Resident Assessment Instrument (RAI) User's Manual, Chapter 2)

Days one through five are optimal but days six through eight are also acceptable, and for some residents may actually be more appropriate... [in regard to choosing an Assessment Reference Date]

The grace days are also provided to offset any incentive that facilities may have to initiate therapy services before the beneficiary is able to tolerate that level of activity.

(Federal Register, July 30, 1999, SNF PPS Final Rule)

Even though projection of anticipated therapy is currently allowed, grace days are still necessary if, for example, the patient is admitted on Wednesday and the first treatment occurs on Friday and a therapist is not available on the weekend. This scenario leaves only one day of therapy, which often does not provide enough information on which to base an estimate of anticipated therapy.

Projection of anticipated therapy services. CMS mentions, as a possible policy change, the elimination of the projection of anticipated therapy services during the 5-day assessment. As discussed above under "grace days," the ability to estimate therapy services is essential when there are limited days available for therapy treatment during the initial assessment period. We believe the RAI User's Manual again provides a solid reason for retaining a provision of the PPS assessment process. It states that the intent of MDS Section T is:

To recognize ordered and scheduled therapy services during the early days of the resident's stay. Often therapies are not initiated until after the end of the observation assessment period. For the Medicare 5-Day or Readmission/Return assessment, this section provides an overall picture of the amount of therapy that a resident will likely receive through the fifteenth day from admission.

We believe that CMS should show evidence that there is a problem with accuracy in Section T of the MDS, if it should decide to eliminate the projection of therapy services. Revisions to the *RAI User's Manual* provide clarification on counting days in Section T and should minimize inaccurate projections.

Designing Pay for Performance (P4P) programs. We agree that a P4P program cannot be limited only to Medicare residents, considering that Part A beneficiaries represent approximately 10 percent of a SNF's residents. For speech-language pathology (including

Mark B. McClellan, MD, PhD July 11, 2005 Page 4 of 4

swallowing disorders), we endorse the adoption of a functional progress measure based on ASHA's National Outcomes Measurement System (NOMS) that was developed in 1994. Voluntary subscribers to the system include inpatient and outpatient settings, of which 260 facilities are SNFs. NOMS uses a seven-point functional progress scale which we believe is much more meaningful than the other five-point systems. We believe the design of effective incentives based on performance (i.e., outcomes) will be a complex process, but it is worthy of serious exploration. One of the reasons for the complexity is that, for residents with the same primary diagnosis, optimal functional progress may be two levels for some residents but four or five levels for others.

Concurrent Therapy

ASHA has not received reports from members of incidents that facilities have attempted to increase productivity by coercing a speech-language pathologist to perform concurrent therapy.

ASHA again expresses its appreciation for the opportunity to comment on proposed changes to the SNF prospective payment system. For further information, please contact Mark Kander, Director of Health Care Regulatory Analysis, at 301-897-0139 or by email at mkander@asha.org.

Sincerely, B. Potter

James G. Potter

Director, Government Relations & Public Policy





JUL 12 2005

Charles N. Kahn III President

July 12, 2005

Dr. Mark McClellan, Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Room 445-G Hubert H. Humphrey Building 200 Independence Ave., S.W. Washington, DC 20201

Re: CMS-1282-P; Comments on Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing

Facilities for FY 2006; Proposed Rule.

Dear Dr. McClellan:

The Federation of American Hospitals ("FAH") is the national representative of privately owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay and long-term care hospitals in urban and rural America, and provide a wide range of ambulatory, acute and post-acute services. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed rule ("NPRM") regarding changes to the prospective payment system for skilled nursing facilities for fiscal year ("FY") 2006.

1. Market Basket Increase

On page 29074 CMS states that, "The FY 2006 market basket increase factor is estimated to be 3.0 percent." "...the payment rates for FY 2006 are updated by a factor equal to the full market basket index percentage." "Tables 2 and 3 reflect the updated components of the unadjusted Federal rates for FY 2006."

The FAH agrees with the 3.0 percent SNF market basket increase to the unadjusted Federal rates for FY 2006.

2. Case-Mix Adjustment and Other Clinical Issues

a. Data Sources and Analysis and Constructing the New RUG-III Groups

On page 29076 CMS states, "...we found that the most viable way to refine the system at the present time would be to add groups to the top of the hierarchy to capture beneficiaries who qualify for both the Extensive Services category and the Rehabilitation Therapy category." "Therefore, we believe that the RUG-III case-mix classification system can provide even more accurate payment for these beneficiaries if refined to create a new RUG-III category for beneficiaries who qualify for both the Extensive Services and Rehabilitation Therapy categories." "...As a result, we are proposing the addition of 9 new RUG-III groups."

The FAH agrees that the construction and addition of the 9 new RUG-III groups will improve the payment system. However, the FAH is not convinced that the enhanced payment system will adequately reimburse medically intensive patients. The FAH encourages CMS to continue to research improving and, if necessary, replacing the RUG system.

b. Development of the Case-Mix Indexes

On page 29077 CMS states, "We developed the case-mix indexes for the proposed refined RUG-III system using the same method used for calculating the initial SNF PPS case-mix indexes. The original staff time studies conducted in 1990, 1995, and 1997 resulted in the assignment of resident-specific and non-resident specific time (minutes) to individual SNF residents. In the initial determination of the case-mix indexes, the residents were classified into the 44-group and the minutes of staff time, nursing, and therapy services, where appropriate, remained associated with those residents."

And on page 29078, "In determining the size of this adjustment, we considered not only the high degree of variability in non-therapy ancillary costs, but also the absence of an outlier policy under the SNF PPS. Accordingly, we looked at the outlier pool established under another post-acute care PPS, the one for inpatient rehabilitation facility (IRF) services, which is set at 3 percent of aggregate expenditures. For the purpose of this refinement, our calculations employed a comparable funding level that could be targeted toward payment of non-therapy ancillaries. Based on this analysis, we are proposing an increase to the nursing component of the case-mix weights (the component that includes non-therapy ancillaries) of approximately 8.4 percent, which equates to approximately 3 percent of aggregate expenditures under the SNF PPS."

The FAH does not agree with this analysis and assumption by CMS. First, the most recent staff time study was conducted in 1997. The FAH recommends that the staff time study be conducted with 2004 and 2005 data. Second, the assumption that the IRF PPS outlier policy percentage is applicable to SNF is not valid. The FAH believes that the non-therapy ancillary costs are not represented in the IRF PPS outliers. Further study and refinement need to occur to more accurately determine non-therapy ancillary costs. Another option that should be considered for 2006 is to implement a SNF PPS outlier

policy which would be more patient cost specific than RUG-III category specific. The 3% increase in aggregate expenditures could be utilized in establishing a pool for SNF outlier payments. An outlier policy would provide some relief for SNFs that are providing for medically intensive patients until the RUGs system can be better refined to account for the high costs of such patients.

3. Proposed Refinements to the Case-Mix Classification System

On page 29080, CMS requests comments on the lookback period. "... [W]e seek comment on the potential savings and other impacts of revising the MDS Manual instructions to include only those special care treatments and programs (MDS Section P1a) furnished to the resident since admission or re-admission to the SNF, similar to the requirement for P1b."

The FAH supports eliminating the lookback period in the SNF. This will, in essence, drive the payment for services provided during the SNF stay only and will not reflect services that the patient received prior to the SNF stay and that no longer reflect the true acuity and medical needs of the patient. Thus, payment to the SNFs will reflect an overall decrease for the days covered by the 5-day MDS PPS assessment. CMS and SNFs will more than likely experience a case-mix shift due to the elimination of the lookback period. However, this change should be implemented in a budget neutral manner. CMS should increase the standardized rate to account for the decrease in payments by elimination of this lookback period.

CMS also requests comments on the elimination of grace days. "...we have received recommendations to decrease or eliminate the grace day period specifically for the 5-day PPS MDS assessment. We invite comments on this specific recommendation as well as decreasing or eliminating the grace periods associated with all PPS MDS assessments."

The FAH does not support the decrease or elimination of grace days for the MDS assessments. SNFs need the flexibility to set the assessment reference date of the MDS during the grace period based upon the patient's needs during that time.

Another policy change that CMS has requested comments on is the elimination of MDS Section T during the 5-day PPS assessment. "Another example of a possible policy change on which we invite comment would be whether it might be appropriate to eliminate the projection of anticipated therapy services during the 5-day PPS assessment."

This policy change would impact system changes to RAVEN, the grouper, and to the RUG system. The FAH supports the elimination of Section T for the 5-day PPS assessment; however, this change would need to occur only after CMS has made the necessary system changes.

On page 29080, CMS is "soliciting comments on the economic impact of the resulting payment changes, as well as their potential impact on beneficiaries' access to quality SNF care."

The FAH encourages CMS to closely monitor patient access to SNFs as related to changes set forth by the SNF final rule.

The FAH believes that changes to the MDS items should be delayed and presented in whole as a proposed regulation. The impact of the MDS changes discussed above would be far reaching and would drastically impact the payment system. The FAH recommends that CMS release the

final rule related to payment only and release a proposed rule to address the MDS changes, keeping in mind that the MDS is currently undergoing an update in MDS version 3.0.

4. Implementation Issues

CMS states on page 29081, "Accordingly, from October 1, 2005, through December 31, 2005, we propose to make payment based entirely on the existing 44-group RUG-III classification system. Beginning on January 1, 2006, we propose to make payment based entirely on the proposed new RUG-53 classification system."

The FAH commends CMS for proposing delaying the implementation of the refined system until January 1, 2006. However, the FAH strongly recommends that CMS not implement any refinement system, including the proposed SNF PPS refinement, until <u>all</u> necessary system changes have been made and tested.

5. SNF Certifications and Recertifications Performed by Nurse Practitioners and Clinical Nurse Specialists

On page 29082 CMS states, "We believe that, even in the absence of a direct employment relationship, an SNF that has an NP or CNS perform these general nursing services is essentially utilizing the NP or CNS in the same manner as it would an employee, so that an indirect employment relationship can be considered to exist. Accordingly, in situations where there is no direct employment relationship between the SNF and the NP or CNS, we propose that an indirect employment relationship exists whenever the NP or CNS not only performs delegated physician tasks, but also provides nursing services under the regulations at 42 CFR 409.21, which include such services within the scope of coverage under the Part A SNF benefit. We believe that this criterion is appropriate, because there would be a potential conflict of interest if an NP or CNS who is engaged in furnishing covered Part A nursing services to an SNF's resident were also permitted to certify as to that resident's need for Part A SNF care. We invite comments on the effects of establishing our proposed distinction in this context."

The FAH agrees with CMS' proposed distinction in this context.

6. Concurrent Therapy

CMS, on page 29083, invites "comment on the most effective way to prevent the abuse of this practice, and to ensure that concurrent therapy is performed only in those instances where it is clinically justified."

One of the biggest challenges that therapists face daily is abiding by different regulations in different acute and post-acute settings – especially for therapists who work in the hospital that has multiple rehab settings. CMS has provided very clear guidelines as to what can be charged and billed and the documentation that must accompany what has been billed in the outpatient setting. The FAH recommends that CMS adopt the outpatient rehabilitation regulations for therapy in the SNF setting and in other post-acute settings. This will allow therapists to focus less on regulatory requirements per setting and more on treating the patients and charging for the therapy on a consistent basis throughout the organization.

7. Proposed Revisions to the SNF PPS Labor Market Areas

The FAH agrees with CMS' proposed move to new CBSA census definitions. We think it is logical that all the prospective payment systems utilize the same census definitions. However, we recommend the change be transitioned over the period of one year. We feel the simplest way to administer this transition would be to blend the CBSA and MSA wage indexes for all SNFs for Federal Fiscal Year 2006.

The transition could also be accomplished by blending the wage indexes of those hospitals that would experience a drop in their wage indexes because of the adoption of the new CBSAs. Any SNF experiencing a decrease in their wage index relative to its FY 2005 wage index because of the labor market-area changes would receive 50 percent of the wage index using the new CBSA definitions and 50 percent of the wage index that the provider would have received under the old MSA standards. This blend would apply to any provider experiencing a decrease due to the new definitions. This is consistent with how CMS implemented this change in the IPPS.

The CBSA definitions would also be utilized for Federal Fiscal Year 2007 and beyond.

8. Qualifying Three-Day Inpatient Hospital Stay Requirement

On page 29099 CMS states, "...with regard to those beneficiaries whose formal admission to the hospital as an inpatient is immediately preceded by time spent in hospital observation status, we invite comments on whether we should consider the possibility of counting the time spent in observation status toward meeting the SNF benefit's qualifying 3-day hospital stay requirement."

The FAH supports CMS' counting of observation days toward the 3-day hospital stay requirement. However, the FAH encourages CMS to clarify how the observation time will be tracked administratively.

9. Regulatory Impact Analysis

The FAH recommends that CMS provide the impact file for SNF PPS similar to the impact file CMS provided for the IPPS. This file needs to include total payments and total days by provider number. The impact on creation of new RUG categories is difficult for facilities to model.

FAH appreciates CMS' review and careful consideration of the comments in this letter, and would be happy to meet, at your convenience, to discuss them. If you have any questions, please feel free to contact Steve Speil at 202-624-1529.

Respectfully submitted,

Charles N. Kahn III, President Federation of American Hospitals

29-H

American Health Care Association

July 12, 2005

1201 L Street, NW, Washington, DC 20005-4014

Main Telephone: 202-842-4444

Main Fax: 202-842-3860 2nd Main Fax: 202-289-4253

Writer's Telephone:
Writer's E-Mail:

202-898-2828 hdaub@ahca.org

www.ahca.org

Steven Chies CHAIR Benedictine Health Systems Cambridge, MN

> Angelo Rotella FIRST VICE CHAIR Friendly Home Woonsocket, RI

> > John Elliot SECRETARY AMFM Inc. Charleston, WV

Rick Miller TREASURER Avamere Health Services Inc. Wilsonville, OR

> Mary Ousley IMMEDIATE PAST CHAIR SunBridge Healthcare Albuquerque, NM

J. Robert Wilson INDEPENDENT OWNERS VICE CHAIR Columbine Health Systems Ft Collins, CO

Howie Groff REGIONAL MULTIFACILITY VICE CHAIR Tealwood Care Centers Bloomington, MN

Edward Kuntz NATIONAL MULTIFACILITY VICE CHAIR Kindred Healthcare Louisville, KY

Solanges Vivens
NONPROPRIETARY
VICE CHAIR
VMT Long Term Care Mgml., Inc.
Washington, DC

Robert Van Dyk ASSISTED LIVING / RESIDENTIAL CARE VICE CHAIR Van Dyk Health Care Ridgewood, NJ

> Mike Bibo MRDD / RESIDENTIAL SERVICES VICE CHAIR RFMS Galesburg, IL

William Levering CHAIR COUNCIL OF REGIONAL VICE CHAIRS Levering Management Inc. Mt. Vernon. OH

Linda Sechovec PRESIDENT OF ASHCAE New Mexico Health Care Assn. Albuquerque, NM

> Hal Daub PRESIDENT & CEO

Mark B. McClellan, MD, PhD Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Room 309-G Hubert H. Humphrey Building 200 Independence Avenue, S.W. Washington, D.C. 20201

Attn: CMS-1282-P

Re: Comments on Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006, Proposed Rule, 70 Federal Register 29070, May 19, 2005, CMS-1282-P

Dear Dr. McClellan:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the proposed rule, *Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006, Proposed Rule, 70* Federal Register 29070, May 19, 2005 CMS-1282-P. AHCA is the nation's leading long term care organization. AHCA and its membership are committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical long term care. AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

AHCA has made several recommendations on the broad array of issues raised by the Centers for Medicare & Medicaid Services (CMS) in the proposed rule. We believe that they support both CMS' and AHCA's ongoing efforts to assure that skilled nursing facility (SNF) care is of the highest quality and that the delivery capacity of AHCA membership is not eroded. We expect that CMS will pay serious attention to our efforts and, working with AHCA, adopt as many of these recommendations as possible. We take the opportunity here to highlight several areas raised that are of

major importance to SNFs and are extensively addressed by AHCA in our comments below.

RUG Refinement

CMS has proposed the creation of 9 new Resource Utilization Group (RUG) categories for Rehabilitation and Extensive Services SNF residents to better account for medically complex patients, and an adjustment to the case-mix weights to better account for non-therapy ancillary service costs.

CMS indicates that it is advancing the proposed changes under its authority in Section 101(a) of the Balanced Budget Refinement Act of 1999 (BBRA) to establish case-mix refinements and that the changes CMS is proposing will represent the final adjustments made under this authority. We agree that CMS cannot make further adjustments to the SNF prospective payment system (PPS) under Section 101(a) and that no further changes will in fact be made pursuant to Section 101(a). AHCA is, however, disappointed that CMS failed to take this opportunity under the BBRA to make substantial changes to significantly improve the SNF PPS.

In the proposed rule, CMS proposes to cut approximately \$510 million from what aggregate SNF payments would have been in FY 2006 without the refinement – i.e. an amount equivalent to the 3 percent market basket update. Research conducted by the Lewin Group and AHCA further suggests that payments for FY 2006 will be \$90.6 million lower in FY 2006 than the proposed rule estimates, and that the adoption of the Office of Management and Budget (OMB) Core-Based Statistical Area (CBSA) designations appears to result in an additional annualized reduction in payments of \$9 million. Given the pivotal role that the Urban Institute report played in the CMS proposed RUG refinement, AHCA urges CMS to complete and release the report to Congress on the SNF PPS and to release the Urban Institute report for public review and to better inform discussions on improving the SNF PPS.

AHCA also is concerned about the impact of the proposed rule on the financial stability of the long-term care sector, particularly as it relates to nursing homes. The proposed reduction in payments and regulatory changes represent a significant cut for SNFs. Given that margins are extremely thin, nursing facilities will have limited ability to absorb the reduction in payments while costs continue to rise.

AHCA recognizes that the design of the proposed rule and the timing of the refinement in part reflect Administration priorities to rein in significant budget deficits. However, AHCA, urges CMS to undertake appropriate adjustments and actively monitor the SNF PPS so that it can ensure that the actual negative economic impact of the proposed rule on SNFs is not greater than that actuarially estimated by CMS. Moreover, CMS should retain the current level of funding in the system to maintain the financial stability of the long term care sector.

In addition, CMS should review its data and methodology on the economic impact of the proposed RUG refinement, given the discrepancies identified by research conducted by the Lewin Group and AHCA, as discussed further in these comments. The economic impact assessment of the proposed rule on FY 2006 aggregate SNF payments is also predicated on the

assumption that CMS will not remove the current look-back provisions in the minimum data set (MDS), nor eliminate the grace period, nor reduce payments for Medicare allowable bad debt.

Indeed, the reduction in payments that facilities will face beginning January 1, 2006 will have a significant impact on providers. Based on analysis by the Lewin Group, average Medicare per diems will fall by approximately \$16 per day (from \$336 per day to \$320 per day) effective January 1, 2006. AHCA proposes a two pronged alternative approach to reducing the impact of this Medicare rate "cliff" whereby CMS factors the adjustment for non-therapy ancillary services (NTAS) variability into the unadjusted nursing case mix component of the rate, and applies an additional appropriate adjustment to the nursing and therapy indices to fully equalize per diem rates over each quarter in FY 2006.

CMS also proposes to make an upward adjustment to the nursing component of the case-mix weights to better account for non-therapy ancillary variability and better account for variability in costs across RUG categories. While a 3 percent adjustment in aggregate expenditures to account for outlier cases may be sufficient in the inpatient rehabilitation facility (IRF) setting, this level of "cushion" does not appear to be sufficient in the SNF setting. The time and motion studies upon which the SNF PPS is based have not been updated, while patient acuity has increased and resource needs and cost of care of residents within RUG categories continues to increase, resulting in inadequate compensation overall and underpayments relative to costs across providers.

AHCA proposes that in addition to the adjustment for non-therapy ancillary variability, CMS allocate an additional pool of funds equivalent to 3 percent of aggregate expenditure to account for the wider variation in resource needs for all patients under the proposed RUG-53 system. The additional pool of funds also would respond to greater resource needs within RUG categories for an interim period until new time and motion studies can update the relevant indices upon which the SNF PPS is predicated.

Clinical Issues

CMS is seeking comment on potential savings from revising the MDS Manual instructions to include only special care treatments and programs provided to SNF patients, and on the reduction or elimination of grace day periods associated with all PPS MDS assessments.

CMS expresses the view that eliminating the 14-day look-back period will help ensure the accuracy of patient classification and eliminate the number of individuals to classify as Extensive Services category based solely on services that were furnished exclusively during the period before the SNF admission. The CMS rationale for eliminating the look-back period is based on reimbursement concerns only, without regard to the impact of removing the look-back on patient assessment, transition of care, care planning and quality measurement. There are strong clinical reasons outlined in our comments for retaining the look-back period. It is AHCA's position that removing the look-back period on MDS Section P1a will negatively impact the quality of care of the beneficiary, care planning, and quality measurement. In addition, a patient that received certain services in the past 14-days can require more intensive nursing services for which SNFs should be appropriately compensated.

The elimination of grace days is also clinically inappropriate. Clinical considerations for retaining grace days should be of paramount importance. AHCA agrees that grace days should be used carefully and in limited circumstances. When properly used, however, they play an important role in providing quality care and receiving adequate reimbursement for that care. They are also an important aspect of accurate MDS assessment, and we fundamentally disagree with decreasing or eliminating the grace day period for any PPS MDS assessments.

Proposed Revision of SNF PPS Geographic Classifications

AHCA is encouraged that CMS is seeking to implement measures that would modify the definition of Metropolitan Statistical Areas (MSAs) to make the payment system more accurately reflect SNF costs associated with local labor market conditions. We do, however, have concerns that CMS may be going beyond its authority under the SNF PPS enabling legislation, the Balanced Budget Act of 1997 (BBA), to apply the Office of Management and Budget (OMB) Core-Based Statistical Areas (CBSAs). In our comments, we provide an analysis and the basis for our conclusion on the issue of authority. But we also focus on ways that CMS, if it has the authority to do so, could work with the new OMB statistical areas to make the payment system better reflect SNF costs associated with local labor market conditions.

As it now stands, the proposal to adopt the OMB CBSA designations fails to correct inherent deficiencies and distortions in the wage index used to adjust SNF payments to reflect local labor market conditions. Implementation of the OMB CBSA designations without addressing other outstanding issues, such as deficiencies in the wage index currently used in the SNF setting, and the lack of methodologies in the SNF PPS for geographic reclassification and a rural wage index floor, will inflict unnecessary unintended effects on SNF providers without improving the accuracy of the payment system.

CMS should develop and implement the four-year phase-in as outlined by AHCA in order to allow SNFs to make appropriate adjustments in their operations, particularly those SNFs that are most dramatically affected by the proposed changes. In addition to a phase-in of the OMB CBSA wage area designations, CMS should begin to develop and implement a SNF-specific area wage index, establish a methodology in the SNF PPS for SNFs to request reclassification to alternate more appropriate local market areas, and include a methodology in the SNF PPS to establish a "rural" floor for the wage index.

SNF Market Basket

Despite developments regarding proposed RUG refinements and proposed revision of SNF PPS geographic classifications, one should not lose sight of the fact that much work remains to be done on other aspects of the PPS system. In particular, CMS needs to turn its attention to improving the SNF market basket. AHCA has urged CMS to engage in a broad-based thorough review of the SNF market basket that would include an analysis of all the weight and price proxy components of the current SNF market basket. To date this process had not occurred, and our concerns remain.

Among our concerns is the fact that outdated weights understate actual costs and cost increases. For example, the weight in the market basket related to pharmacy is only 3 percent of costs, while in terms of actual charges, pharmacy accounts for approximately 13 percent. In addition, the price index used to measure changes in the wages of SNF workers, the Employment Cost Index (ECI), is a broad measure of nursing home industry wage changes, but is not specific to SNFs. Furthermore, the current market basket does not capture the large cost increases SNFs have faced in purchasing liability insurance or reinsurance since there is no weight for professional liability costs and therefore no index to measure price changes for that weight. CMS needs to undertake a major effort to correct these deficiencies to achieve its overall goal of improving the accuracy of the SNF PPS.

Qualifying 3-Day Hospital Stay Requirement

CMS should exercise the authority of the Secretary to eliminate the requirement of the 3-day stay as a prerequisite for SNF Part A care. CMS' reluctance to address elimination of the 3-day stay requirement may stem from concerns about cost, an incomplete understanding of the gains for Medicare beneficiaries that would result from modifying the 3-day stay requirement, and an absence of objective data. Thus, as part of a process to effectuate the removal of the 3-day stay, CMS should at a minimum, initiate a demonstration to evaluate the implications of selectively eliminating the 3-day inpatient hospital stay requirement, as outlined in our comments.

In the interim, while the 3-day stay rule remains, CMS should require hospitals, which are the only entities privy to all the hospital records, to attest to the existence of a *bona fide* 3-day qualifying stay -- an attestation that the SNF can rely on in good faith and that only the hospital can provide. If the attestation later turns out to be incorrect, the beneficiary and the SNF should be held to be without fault and bear no financial responsibility for the Part A SNF stay. As long as the rule is in effect, it is essential that the 3-day stay be correctly computed to assure beneficiary access to post acute care and services.

In addition, for the reasons provided below in our comments, AHCA's position is that all days spent in a hospital prior to the DRG based stay should count toward the calculation of the 3-day stay. AHCA has long argued this to CMS and has been part of a coalition of 18 associations and groups who have collectively argued to CMS that beneficiaries' access to care and services continues to be jeopardized by the interpretation of federal law that denies Medicare reimbursement for SNF stays when the beneficiaries have been hospitalized for three or more days. In short, all time spent in the hospital, whether it is in emergency rooms or observation stays, should be counted in the calculation of the 3-day stay.

Consolidated Billing

In the proposed rule, CMS has invited public comment in identifying codes for further exclusions from PPS consolidated billing of services within four categories specified by Section 103 of the BBRA: chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices. CMS also believes that, given the related report

language of the BBRA legislation, the services must be characterized by high cost and low probability in the SNF setting and must represent recent medical advances.

We believe that certain chemotherapies that now otherwise qualify for exclusion under the criteria noted above were not part of original BBRA list either because appropriate information was not available at the time, the items are new and their wide-spread use post-dates BBRA, or Congress inadvertently failed to include them. These drugs are chemotherapy drugs, or cancer chemotherapeutic agents or adjuncts to such agents that are high cost and have low probability of use in the SNF setting.

AHCA has provided detailed listings of these drugs which meet CMS' tests and which CMS should proceed to exclude. In addition, AHCA is recommending a change in the site of service policy that permits the unbundling of excluded services only if those services are provided in a hospital. Certain of the intensive diagnostic or invasive procedures in question are no longer specific to the hospital setting because of changes in medical practice and technology but remain outside the scope of SNF services. It is well within CMS' regulatory purview to update the policy to include providers, in addition to hospitals, who are now commonly providing these intensive diagnostic and invasive procedures.

Pay-For-Performance

CMS states that pay-for-performance is a tool that could provide additional support to improve the quality of care provided in nursing homes, but indicates that development of such a tool raises many complex issues. AHCA recognizes that designing a pay-for-performance system for SNFs involves many complex issues, the most critical of these are reliable and sufficient funding and the capability to measure performance. Since the ability to determine funding requirements is contingent on current and projected performance, the issue of valid and reliable quality measures is paramount.

Last year AHCA began an extensive internal policy making process to develop a pay-for-performance policy that would best serve the entire spectrum of long term care quality improvement objectives. We determined that a pay-for-performance program should be a vehicle that encourages quality and rewards providers based on improving care and exceeding certain benchmarks. In constructing a pay-for-performance program based on this concept, the best way to measure quality needs to be considered and incorporated in the program. In our comments, we have provided guidelines that address the pay-for-performance considerations that are the most relevant to SNFs and look forward to working with CMS on the development of appropriate quality measures as a basis for a pay-for-performance program.

Development of An Integrated Approach to Payment and Delivery of Post Acute Care

AHCA supports Medicare payment and delivery system adjustments that ensure the most appropriate placement for Medicare beneficiaries needing post-acute care. Such system improvements may include implementing a uniform patient assessment instrument for post-acute care settings and ensuring that financial incentives result in the best clinical post-acute placement

for patient. All improvement must be patient-centric, i.e. based solidly on patient characteristics and outcomes, and be based on a common patient-centered quality assessment system.

On June 16, 2005, the U.S. House of Representatives Ways and Means Health Subcommittee held a hearing on this topic. At the hearing, Mary Ousley, R.N., Immediate Past President of AHCA, made clear our support of the concept. Ms. Ousley stated:

First and foremost, it is essential for CMS to develop a patient centered core uniform screening and assessment tool for post acute care, and a uniform integrated payment system based on this comprehensive assessment tool. But until CMS can finalize and apply a uniform system, it can do a better job of placing post acute patients in the most appropriate care settings. For example, AHCA supports the use of hospital discharge planning as a starting point to standardize post acute assessment tools.

As part of this effort, AHCA urges CMS to develop a common patient-centered quality assessment system as a part of any post-acute healthcare delivery structure. This quality assessment system would provide consumers with consistent, comparable data necessary to enable them to make informed decisions regarding the most appropriate placement of family and loved ones based on patient quality outcomes across post-acute settings. As we discuss in our comments, technology, such as advanced hospital discharge planning tools, has and can continue to make a huge contribution to consumer decisions regarding the appropriateness of care placement.

AHCA applauds CMS' conclusion that improved information technology is critical for the post-acute and long term care systems and strongly agrees that today and in the future there should be requirements for information exchange among long term care settings (e.g. skilled nursing facilities and other post-acute care settings, assisted living settings, home health care, independent living settings, acute care and ambulatory care settings) that would support a unified post-acute care PPS. This is especially true as care evolves from a static incident reporting health system to a dynamic disease management system where complete resident patient health and trends are taken into consideration during the process of care planning. As CMS states, such an information flow would be critical to the success of a comprehensive assessment tool that would span post-acute care settings.

CMS should bring to bear AHCA's expertise and knowledge as the agency advances such initiatives. AHCA has a wide array of information technology initiatives that could inform the development of the assessment tool noted above and the related unified post-acute care PPS.

Conclusion

In conclusion, while AHCA believes that CMS's proposals could be significantly improved, we nevertheless appreciate the attention that CMS has given to our concerns and the agency's willingness to work with us to craft a package of refinements that addresses the economic stability issues that underlie our historical opposition to the notion of linking refinement to a payment cliff. AHCA has opposed RUG refinements for many years based largely on the assumption that implementation would be accomplished by removing the funding represented by

the add-ons which would be inconsistent with AHCA's mission of continuous quality improvement. With CMS' creation of a workable framework for addressing its responsibilities under BBRA regarding add-ons, the industry looks forward to productive engagement with CMS on a plethora of significant payment policy issues which have been overshadowed by the add-on battles.

The demand for high quality post acute skilled care is rapidly growing as we age and see acuity increase. We appreciate the challenge of designing a post acute care system and payment system that balances resident desires and needs, with fair reimbursement for nursing facility costs, and continuous improvement in the delivery of quality care. An appropriate balance should be achievable between legitimate budget concerns and the cost of providing quality care.

It is expensive and labor-intensive to deliver quality long term care. Such care will also not get less expensive in the future. Adequate and stable financing enables the industry to improve quality of care and retain a skilled workforce. Diluting reimbursement defeats the mission of quality care.

So our comments are founded on the solid collaboration that has already been demonstrated by our work with dozens of leaders and staff at CMS, HHS, OMB and in Congress, that, within the context of this budget canopy, the mission of continuing to deliver better care will be furthered by adoption of equitable refinement with full consideration and incorporation of AHCA's recommendations.

Again, we look forward to working with you, as CMS and AHCA both continue our mutual efforts to provide the best possible care for America's frail elderly and disabled.

incerely,

President and CEO

We recognize your leadership as least to the close working relationalist we have had during relationalist we have had during the last couple of months.

Table of Contents

Section	Content	Page
	AHCA Recommendations in Brief	10
	AHCA Detailed Comments	14
I.	Proposed Refinements to the RUG Case-Mix Classification System	14
II.	Clinical Issues.	26
III.	Proposed Revision of SNF PPS Geographic Classifications	32
IV.	The SNF Market Basket	41
V.	Consolidated Billing	46
VI.	Qualifying 3-Day Hospital Stay Requirement	60
VII.	Pay-For-Performance	71
VIII.	Development of An Integrated Approach to Payment and Delivery of Post	
	Acute Care	74

AHCA Recommendations In Brief

AHCA Recommendations on the Proposed Refinement to the RUG Case-Mix Classification System (See pages 14 to 25):

- CMS should adopt a two pronged approach to smooth out the reduction in payments that facilities will face beginning January 1, 2006, where by,
 - 1. CMS factors the adjustment for non-therapy ancillary services (NTAS) variability into the unadjusted nursing case mix component of the rate, and
 - 2. applies an additional appropriate adjustment to the nursing and therapy indices to fully equalize per diem rates over each quarter in FY 2006;
- CMS should review the data and methodologies it used to estimate the economic impact
 of the proposed rule as it appears to be underestimate the negative impact of the
 refinement;
- CMS should apply appropriate adjustments to the SNF PPS to offset any reduction in SNF aggregate payments due to errors in the estimation of the economic impact of the proposed RUG refinement, elimination of the look-back provision, or implementation of the bad debt rule, in order to ensure the viability and sustainability of the long term care sector.
- CMS should further adjust the case-mix classification system refinement in the proposed rule as it is insufficient to cover higher costs associated with medically complex patients, high variability in NTAS costs, high variability in costs across RUG categories, and increased resource needs associated with increased resident acuity within RUG categories; and
- CMS should complete the required report to Congress on SNF payment issues, and release the Urban Institute report for public review, given the pivotal role that this report played in CMS' proposed refinement to the SNF PPS.

AHCA Recommendation On The Look-Back Period For MDS Section P1a, Grace Days, And Concurrent Therapy (See pages 26 to 31):

- CMS should not decrease or eliminate the 14-day look-back period at MDS Section P1a because of the negative impact of elimination on care quality, care planning and quality measurement:
- CMS should not decrease or eliminate grace day periods associated with any PPS MDS
 assessments including the 5-day PPS assessment because of the negative impact of
 elimination on care quality, care planning and quality measurement;
- CMS should continue to thoroughly examine the incidence of "routine use of grace days" to identify specific areas of concern and appropriate modifications; and

• CMS should not issue additional regulations addressing concurrent therapy, given the systems already in place to ensure that concurrent therapy meets the skill level and is clinically appropriate for the given beneficiary.

AHCA Recommendations on the Proposed Revision of SNF PPS Geographic Classifications (See pages 32 to 40):

- CMS should proceed to develop and apply a SNF-specific area wage index, effective no later than FY 2007, and should immediately request the resources necessary to accomplish this;
- CMS should give SNFs the ability hospitals have to reclassify to more appropriate areas, by developing the SNF-specific area wage index required by Congress as the basis of geographic reclassification for SNFs;
- Concurrent with the development of a SNF-specific wage index, CMS should set in place the procedures for SNF geographic reclassification;
- CMS should include methodology in the SNF PPS to establish a "rural" floor for the wage index, such that, as in the case of hospitals, the area wage index applicable to any SNF that is not located in a rural area may not be less than the area wage index applicable to SNFs located in rural areas (or pseudo-rural areas in the case of all urban states); and
- If CMS takes the position that it has the authority to apply the OMB CBSA area wage designations, CMS should develop and implement the four-year phase-in as outlined by AHCA in order to allow SNFs to make appropriate adjustments in their operations, particularly those SNFs that are most dramatically affected by the proposed changes.

AHCA Recommendations on the SNF Market Basket (See pages 41 to 45):

- CMS should base the weights used in calculating the market basket update on the most up to date cost data available;
- CMS should revise and reweight the SNF market basket with greater frequency on the same schedule as the hospital market basket;
- CMS should complete the Congressionally-mandated study on how frequently the hospital market basket should be updated, and update the SNF market basket weights with the same frequency using submitted cost report data;
- CMS should evaluate other options for measuring changes in the price of wages and salaries for SNFs. Specifically, CMS should engage in a data collection effort aimed at collecting SNF-specific labor data for the purposes of creating a price proxy for labor costs in SNF; and

• CMS should study the effect of adding a separate weight for professional liability costs. CMS should work with the SNF industry to determine how the weight should be calculated, given the various financing arrangements SNFs have, and to develop an appropriate price index.

AHCA Recommendations on Consolidated Billing (See pages 46 to 59):

- CMS should exclude from the SNF PPS consolidated billing certain items and services qualified for exclusion under the BBRA criteria as recommended by AHCA. In addition, they were not part of the 1995 base year costs and were not on the original BBRA list because appropriate information was not available at the time, or the items are new and their wide-spread use post-dates BBRA, or Congress inadvertently failed to include them; and
- CMS should adapt its policy on consolidated billing exclusions to encompass changes in medical practices.

AHCA Recommendations on the 3-Day Stay Requirement for SNF Part A Post Acute Care (See pages 60 to 70):

- CMS should enable SNFs to rely in good faith on a hospital attestation that the 3-day stay requirement has been met. If the attestation later turns out to be incorrect, the beneficiary and the SNF should be held to be without fault and bear no financial responsibility for the Part A SNF stay;
- CMS should include all time spent by a beneficiary in an acute care hospital in the calculation of the 3-day stay requirement;
- CMS should exercise the discretion of the Secretary to eliminate the requirement of qualifying 3-day stay requirement; and
- CMS should, at a minimum, initiate a demonstration to evaluate the implications of selectively eliminating the 3-day inpatient hospital stay requirement.

AHCA Recommendations on the Development of a Pay-for-Performance System (See pages 71 to 73):

- CMS should work in conjunction with the long term care profession in its development of any pay-for-performance methodology in order to ensure that the system best measures quality outcomes for long term care patients and residents and facilitates further quality improvements;
- CMS should develop a pay-for-performance program that is flexible enough to allow for changes in the customer's expectation of quality as well as changes in quality outcomes brought about by technology and advances in medicine; and

 CMS needs to evaluate and make public the impact on pay-for-performance from changes brought about by the use of MDS 3.0 prior to program adoption and implementation.

AHCA Recommendations On The Development of An Integrated Post-Acute Payment and Delivery System (See pages 74 to 80):

- CMS should complete the mandated report to Congress due January 1, 2006, on the development of instruments to assess the health and functional status of beneficiaries using post-acute care and other specified services. CMS should involve nursing facility experts on patient assessment as instrument(s) are finalized, tested and revised and actively involve AHCA in the development of an integrated post-acute payment and delivery system;
- CMS should work on developing an integrated post-acute payment system that is based on a uniform patient assessment instrument for post-acute care settings and ensures that financial incentives result in the best clinical post-acute placement for the patient;
- In the interim, CMS should make changes within the existing systems that would better align financial incentives with clinical placement decisions. These include tightening and enforcing new and existing certification criteria for IRFs and LTCHs, and enhancing the role of the Quality Improvement Organizations (QIOs) in reviewing appropriateness of patient placement;
- CMS should use hospital discharge planning as a starting point to standardize post-acute assessment tools. For patients with prior hospital stays, CMS should continue to apply hospital discharge planning that is already required by law and regulations;
- As CMS develops health information technology for use by nursing homes, CMS should include nursing homes in the developmental process and provide opportunities throughout the developmental process for nursing homes to offer its input and expertise;
- CMS should assist nursing facilities to upgrade and improve their information technology infrastructure by providing funding and technical assistance; and
- CMS should evaluate the need for continued MDS 3.0 development and validation given the CMS goal of creating a uniform assessment tool.

AHCA Detailed Comments

I. Proposed Refinement to the RUG Case-Mix Classification System:

AHCA Recommendations on the Proposed Refinement to the RUG Case-Mix Classification System:

- CMS should adopt a two pronged approach to smooth out the reduction in payments that facilities will face beginning January 1, 2006, where by,
 - 1. CMS factors the adjustment for non-therapy ancillary services (NTAS) variability into the unadjusted nursing case mix component of the rate, and
 - 2. applies an additional appropriate adjustment to the nursing and therapy indices to fully equalize per diem rates over each quarter in FY 2006;
- CMS should review the data and methodologies it used to estimate the economic impact
 of the proposed rule as it appears to be underestimate the negative impact of the
 refinement;
- CMS should apply appropriate adjustments to the SNF PPS to offset any reduction in SNF aggregate payments due to errors in the estimation of the economic impact of the proposed RUG refinement, elimination of the look-back provision, or implementation of the bad debt rule, in order to ensure the viability and sustainability of the long term care sector.
- CMS should further adjust the case-mix classification system refinement in the proposed rule as it is insufficient to cover higher costs associated with medically complex patients, high variability in NTAS costs, high variability in costs across RUG categories, and increased resource needs associated with increased resident acuity within RUG categories; and
- CMS should complete the required report to Congress on SNF payment issues, and release the Urban Institute report for public review, given the pivotal role that this report played in CMS' proposed refinement to the SNF PPS.

Discussion

As part of the notice of proposed rulemaking, the Centers for Medicare & Medicaid Services (CMS) invites comments on the agency's proposed refinement to the skilled nursing facility (SNF) prospective payment system (PPS). CMS has proposed the creation of 9 new Resource Utilization Group (RUG) categories for Rehabilitation and Extensive Services SNF residents to better account for the costs of medically complex patients, as required in section 101 of the Balanced Budget Refinement Act (BBRA). CMS also is proposing an adjustment to the case-mix weights to better account for non-therapy ancillary services under CMS' authority provided in Section 1888(e)(4)(G)(i) of the Social Security Act to establish an appropriate adjustment to account for case mix in order to maintain access and quality of care for high-acuity patients.

CMS indicates that it is advancing the proposed changes under the agency's authority in section 101(a) of the BBRA to establish case-mix refinements and that the changes CMS is proposing will represent the final adjustments made under this authority. We agree that CMS cannot make further adjustments to the SNF PPS under Section 101(a). AHCA is, however, disappointed that CMS failed to take this opportunity under the BBRA to make substantial changes to significantly improve the SNF PPS.

The American Health Care Association (AHCA) is concerned about the impact of the proposed rule on the financial stability of the long-term care sector, particularly as it relates to nursing homes. By holding aggregate SNF payments in fiscal year (FY) 2006 at the same level as in FY 2005, the proposed rule cuts approximately \$510 million from what aggregate SNF payments would have been in FY 2006 without the refinement - i.e. an amount equivalent to the 3 percent market basket update. Given that margins are extremely thin, nursing facilities will have limited ability to absorb the reduction in payments while costs continue to increase. Research conducted by the Lewin Group and AHCA further suggests that payments for FY 2006 will be \$90.6 million lower in FY 2006 than the proposed rule with the June 28, 2005 amendments estimates, and that the adoption of the Office of Management and Budget (OMB) Core-Based Statistical Area (CBSA) designations appears to result in an additional annualized reduction in payments of \$9 million. While AHCA recognizes that the design of the proposed rule and the timing of the refinement in part reflect Administration priorities to rein in significant budget deficits, AHCA urges CMS to undertake appropriate adjustments to the SNF PPS so that it can ensure that the negative economic impact of the proposed rule on the SNFs is not greater than that estimated by CMS. Moreover, CMS should ensure that the current level of funding is retained in the system to maintain the financial stability of the long term care sector.

The estimation of the economic impact of the proposed rule on FY 2006 aggregate SNF payments is also predicated on the assumption that CMS will not remove the current look-back provisions in the SNF Minimum Data Set (MDS), nor eliminate the grace period, nor reduce payments for Medicare allowable bad debt. In order to ensure the viability and sustainability of the long term care sector, AHCA recommends that any changes in these provisions that would reduce aggregate payment to SNFs be offset by adjustment to the SNF PPS to counterbalance these provisions.

AHCA is concerned that the proposed Medicare reimbursement reduction – or rate "cliff" - will have a significant impact on selected providers when the RUG-53 system is implemented in the second quarter of FY 2006. Based on analysis by the Lewin Group, average Medicare per diems will fall by approximately \$16 per day (from \$336 per day to \$320 per day) effective January 1, 2006. AHCA proposes a two-pronged alternative approach to reduce the impact of this Medicare rate "cliff" whereby CMS factors the adjustment for non-therapy ancillary services (NTAS) variability into the unadjusted nursing case mix component of the rate, and applies an additional appropriate adjustment to the nursing and therapy indices to fully equalize per diem rates over each quarter in FY 2006, such that they would be approximately equal to the average for the entire year, and there by prevent the precipitation of a payment cliff on January 1, 2006, when case-mix refinement is enacted.

In the proposed rule, CMS proposes to make an upward adjustment to the nursing component of the case-mix weights to better account for non-therapy ancillary variability and better account for variability in costs across RUG categories. While a 3 percent adjustment in aggregate expenditures for outlier cases may be sufficient in the inpatient rehabilitation facility (IRF) setting, it does not appear to be sufficient in the SNF setting for three reasons. First, IRF outlier payments are relatively well targeted, while the proposed SNF case-mix classification refinement adjustment is much more diffuse. Second, the time and motion studies upon which the SNF PPS is based have not been updated, while patient acuity has increased. Thirdly, resource needs and cost of care of residents within RUG categories continue to increase, resulting in inadequate compensation.

AHCA proposes that in addition to the adjustment for non-therapy ancillary variability in the proposed rule, CMS allocate an additional pool of funds equivalent to 3 percent of aggregate expenditure for the wider variation in resource needs for all patients under the proposed RUG-53 system. The additional pool of funds would also respond to greater resource needs within RUG categories for an interim period until new time and motion studies can update the relevant indices upon which the SNF PPS is predicated. During the interim period, CMS should: initiate research to update the time and motion studies; develop and institute appropriate policies in the SNF PPS to take prepare the groundwork to fully take into account outlier patients, disproportionate share facilities, and capital pass-through for new technology; establish a new SNF-specific wage index; review and update the SNF market basket; and develop a SNF PPS that more accurately aligns SNF payments to costs.

A. Methodological Weaknesses of the Proposed Refinement

The FY 2006 SNF PPS proposed rule details CMS' proposed modifications to the SNF PPS to better account for medically complex patients and to better account for non-therapy ancillary services. The proposed rule notes that analysis by the Urban Institute and CMS continues to show that non-therapy ancillary costs are higher for Medicare beneficiaries in Extensive Services RUG-III categories than for those in other categories. CMS argues that the most viable way to refine the current RUG-III system would be to add 9 additional categories to the existing 44 RUG-III categories. These new categories would capture beneficiaries who qualify for both the Extensive Services and Rehabilitation Therapy and create a 53 RUG-III (RUG-53) group system. 70 Federal Register 29076.

1. Current And Proposed SNF PPS Poorly Accounts For NTAS Variation

In 2001, CMS retained the Urban Institute to undertake research in support of making refinements to the SNF PPS case-mix classification system under Section 1888(e)(4)(G)(i) of the Social Security Act and under Section 311(e) of the BIPA. As part of this analysis, "Urban found that the addition of a combined Rehabilitation plus Extensive group improved the predictive power of the model". 70 Federal Register 29076. Using 2001 data, the Urban Institute found that the R² for NTAS per diem costs improved to 9.5 percent using its RUG-58 model, up from an R² of 4.1 percent under the current RUG-44 model. Further analysis by the Urban Institute of a separate validation sample, increased the R² to 10.3 percent. With only 10.3 percent of the variation in the NTAS per diem costs explained using the RUG-58 model, the addition of 9 new categories for Rehabilitation and Extensive Services does not go very far in

improving the SNF PPS case-mix classification system to account for NTAS. Given the pivotal role that the Urban Institute report played in the CMS proposed refinement, AHCA requests that CMS complete and release the report to Congress on SNF payment issues and release the Urban Institute report for public review and to better inform discussions on improving the SNF PPS. ¹

2. AHCA Research Confirms Weakness Of Proposed Refinement

In its comments to CMS on the FY 2002 SNF PPS proposed rule, AHCA noted the difficulty in being able to provide meaningful comments on possible approaches to refining the case-mix system, without access to the same data that CMS used to undertake its analysis and which the agency will use to study alternatives and propose refinement. Because CMS did not make this data accessible, AHCA retained the Lewin Group to obtain the relevant data and undertake analyses that would be necessary to analyze and comment on a proposed refinement to the current RUG-44 based system.²

Based on research conducted by the Lewin Group and AHCA, AHCA is concerned about the inability of the proposed refinement to adequately predict and allocate payments for NTAS. Analysis by the Lewin Group confirms the inherent weakness of the current RUG-44 system and the proposed RUG-58 and RUG-53 systems in accounting for variation in NTAS. Of particular concern to AHCA is the very poor job in explaining NTAS per diem costs for the majority of SNFs (i.e. freestanding SNFs) of both the current RUG-44 system and the proposed RUG-53 system. Analysis by the Lewin Group showed that the R² for freestanding SNFs was only 3.6 percent under the RUG-53 model. Given that freestanding SNFs account for over 88 percent of Medicare patient days, neither the current system nor the proposed RUG-53 system adequately capture NTAS costs in the payment system for freestanding SNFs.

AHCA also continues to be concerned about the inability of the current system and the proposed refinement to appropriately reimburse SNFs for their overall costs. Analysis by the Lewin Group found that the RUG-53 system accounts for only 16.1 percent of the variation in total per diem costs. The explanatory power of the SNF PPS is substantially weaker than that in other settings as it relies solely on patient classification for allocating payments. Payment rates for other types of providers, such as hospitals, have adjustments built into the payment system to

¹ The Benefits Improvement and Protection Act (BIPA) of 2000 — Section 311(e) required that the Secretary of HHS conduct a study of the different systems for categorizing patients in Medicare skilled nursing facilities in a manner that accounts for the relative resource utilization of different patient types; and not later than January 1, 2005 submit to Congress a report on the study which shall include recommendations regarding changes in the law as may be appropriate. CMS contracted with the Urban Institute to undertake research in support of this report.

The analysis by the Lewin Group is based on linked 2001 SNF claims, MDS, and cost report data. A 10 percent sample of approximately 200,000 cases was used. Some of the analysis was also undertaken using a 100 percent sample (the full universe of data), with essentially identical results. Simulations by the Lewin Group examined how well RUG-44, RUG-53, and RUG-58 explained NTAS and total cost per diems. Per diem costs for the various cost components (except routine) were computed by multiplying charges on claims by the appropriate ratio of costs to charges taken from the corresponding SNF cost report. Routine costs were computed using a more complex methodology. Total costs were computed as the sum of all 12 cost components. NTAS costs were computed as total cost less routine and speech, physical, and occupational therapy costs. In the RUG-44 models, the Lewin Group used the RUG-44 assignment on individual claims. For RUG-53 and RUG-58 models, RUGs were assigned based on the Lewin grouper which incorporates much of the CMS RUG-58 grouper program.

take into account higher costs associated with outliers, intern and residents at teaching hospitals, disproportionate share hospitals, and capital pass-through for new technology.

In contrast to the SNF PPS, the Lewin Group found that patient classification alone explained approximately 59.5 percent of the variation for inpatient hospitals and 26.2 percent at long term care hospitals (LTCHs). When patient classification together with other payment adjustments are included, the explanatory power of the payment systems improved to 77.5 percent in inpatient hospitals, 86.4 percent in LTCHs, and 57.8 percent in IRFs. Given the vast divergence between SNF costs and payments under the current and proposed PPS, AHCA notes for the record our interest in working with CMS to develop and implement an adequate payment system that more accurately reflects SNF costs.

3. Outliers Play An Important Role In Explaining NTAS Costs

Outliers play a significant role in driving NTAS costs. In a simple experiment where claims with NTAS per diem costs greater than \$500 were flagged, the Lewin Group was able to improve the R² for the NTAS per diem cost model to 39.3 percent, and for the total per diem cost model to 35.5 percent. All of the improvement in the explanatory power of the NTAS and total costs models were captured by the flag on the NTAS or total outlier cost. The high R² of the models with the outlier flag suggests that a small number of claims have high explanatory power, or conversely, that the SNF payment system fails to track SNF costs adequately when outliers are not accounted for explicitly. AHCA would like to work with CMS to develop an appropriate outlier policy.

4. Future Changes to SNF PPS Require Additional Study

CMS has a number of studies either underway or in the pipeline that could dramatically impact the SNF PPS. New nursing and therapy time and motion studies, ongoing development of MDS 3.0, the impact of new information technology and consolidated health information system standards such as the Systemized Nomenclature Of Human and Veterinary Medicine (SNOMED), the proposed development of a post-acute assessment tool, the refinement of quality measures and the adoption of pay-for-performance, among others, will dramatically impact the cost and delivery of care in SNFs and necessitate modifications in the SNF PPS.

Furthermore, CMS notes that "additional research may identify more comprehensive modifications, [but] it is not currently known when the results of this research would become available." 70 Federal Register 29102. Such additional research could in very short order have led to the development of a more extensive refinement to the SNF PPS that could have dramatically improved the SNF PPS to more accurately align SNF payments and costs. As noted in the proposed rule, CMS considered and AHCA would have supported a deferment of the proposed refinement until CMS evaluation of longer-range, more comprehensive changes to the SNF PPS was completed. 70 Federal Register 29102. This further highlights the need for CMS to release the Urban Institute report to provide information and facilitate informed dialogue for the evolution and improvement of the SNF PPS.

5. Proposed Refinement Appears To Meet Requirements Of BBRA

Despite the weaknesses in the proposed refinement, CMS indicates that it is advancing the proposed changes under its authority in Section 101(a) of the BBRA to establish case-mix refinements and that the changes CMS is proposing will represent the final adjustments made under this authority. AHCA agrees that CMS cannot make further adjustments to the SNF PPS under Section 101(a) and that no further adjustments will be made pursuant to Section 101(a).

B. Additional Weaknesses of the Proposed Rule

1. CMS Asserts Zero Net Impact In SNF Aggregate Spending In FY 2006

CMS asserts that the proposed rule will have no net impact on SNF aggregate spending in FY 2006. In determining the impact of the proposed rule, CMS notes that the add-ons to the SNF PPS would have represented approximately \$1.4 billion in payments to SNFs were they to have been in effect for all of FY 2006. In addition, the 3.0 percent increase in the market basket is estimated to increase aggregate payments to SNFs by approximately \$510 million in FY 2006. While elimination of the add-ons in the last three quarters of FY 2006 would reduce SNF payments by approximately \$1.02 billion, CMS notes that an increase in the nursing component of the case-mix weights by 8.85 percent that would increase SNF payments by approximately \$510 million together with \$510 million from the market basket update, would offset the estimated loss of the add-ons and by CMS' calculations results in zero net impact on SNF aggregate spending in FY 2006.

2. Zero Net Impact Assertion Appears To Be Inaccurate

Although AHCA has a number of concerns about the proposed rule, AHCA is particularly concerned that the estimate of the economic impact of the proposed rule is inaccurate. Analysis by the Lewin Group indicates that the proposed rule with the amendments posted on June 28, 2005, further reduces payment to SNFs in FY 2006 by about \$1.90 per patient day compared to what they were in FY 2005. This translates to an additional payment shortfall of an estimated \$90.6 million in FY 2006.

AHCA also urges CMS to review its calculations related to the SNF wage indices, both the MSA-based index and the CBSA-based index. In terms of Medicare patient day weighted per diems (pre- and post- October 1, 2005), analysis by AHCA using 2002 SNF claims data shows that the adoption of the OMB CBSA designations will result in a 17¢ reduction in the average SNF (Medicare patient day weighted) per diem compared to under the OMB Metropolitan Statistical Area (MSA) designations. This corresponds to an estimated payment shortfall of about \$9 million. Though the discrepancy is relatively small, given that Section 1888(e)(4)(G)(ii) of the Act requires that CMS apply the wage index in a manner that does not result in aggregate payments that are greater or lesser than would otherwise be made in the absence of the wage adjustment, the wage index adjustment proposed by CMS appears to fail the revenue neutrality test. 70 Federal Register 29090.

Though the payment shortfalls identified by the Lewin Group and AHCA could be due to differences in data or estimation methodologies, it could also be indicative of a small though consistent negative bias in the case-mix weight indices, the wage indices, or other aspects of the methodology used in the proposed rule. AHCA requests CMS reexamine the underlying data and computation methods, and remove any undo biases.

3. Proposed Budget Neutrality Adjustments Are Adequate, Not Ideal

On June 29, 2005, CMS updated data used in the proposed rule to project the effect of the changes to the case mix weights and rates using more recent 2001 data, and corrected a mathematical error associated with the therapy case mix weights. The 3.05 percent adjustment in the nursing case-mix index and the 20.75 percent adjustment in the therapy case-mix index that were put in place in order to preserve budget neutrality have the undesirable effect of skewing the overall distribution of payments and payments rates at the RUG level from where they would otherwise have been without the budget neutrality adjustment. Alternatively, CMS could have applied the budget neutrality adjustment by means of an increase in the FY 2006 unadjusted federal per diem rates for all four rate components (nursing case-mix, therapy case-mix, therapy non-case-mix, and non-case mix) by an estimated 6.62 percent. In addition to being far simpler, this approach also would not have skewed the distribution of RUG payments and payment rates.

CMS, however, appears to argue that adjustments can only be made to the nursing case-mix and therapy case-mix indices directly. While the proposed budget neutrality adjustments appear to be consistent with overall aggregate payments, relative payments are nevertheless somewhat distorted.

4. Look-Back Critical In Developing Care Plan And Providing Adequate Payment

The economic impact estimate of the proposed rule is also predicated on the assumption that CMS will not modify the underlying basis of the SNF PPS - the use and interpretation of the Minimum Data Set (MDS) in the SNF PPS. The look-back on the MDS into the previous hospital stay allows a facility access to important information needed to properly assess the resident's condition and adequately plan for the appropriate level of care. Furthermore, elimination of the look-back will impede a nursing facility's ability to develop an appropriate care plan for the resident and penalize facilities that must commit substantial resources within the first few days after admission when patients are in the most unstable and resource-intensive state and require a significant level of skilled nursing care for monitoring and treatment of symptoms related to their stay in the hospital.

The look-back provision was not established to determine that a particular service was delivered but rather to reflect that the types of patients that entered the SNF required more intensive care. Without the look-back provision the SNF will still provide the same level of care, but will not be able to be adequately compensated for that level of ongoing care until the 14-day assessment is performed. A more detailed discussion of the importance of the look-back on patient assessment, transition of care, care planning, and quality measurement can be found in Section II – Clinical Issues.

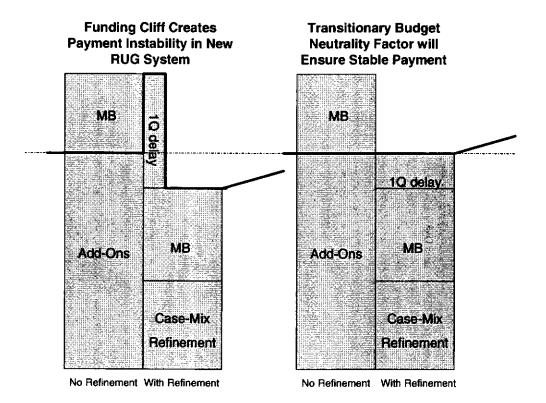
5. The SNF Medicare Payment Cliff

AHCA is concerned that the implementation of the proposed rule as currently designed will have an undesirable destabilizing effect for numerous providers when the refinement is introduced in the second quarter of FY 2006. Based on an analysis by the Lewin Group, average Medicare per diems will fall by approximately \$16 per day (from \$336 per day to \$320 per day) effective January 1, 2006. AHCA recommends that CMS develop an alternative implementation approach that would smooth out or stabilize rates by eliminating the Medicare rate cliff during FY 2006 (See Chart 1 below), and thereby help ensure the consistency of SNF payments.

AHCA recommends a two-pronged approach to smoothing out the cliff. First, rather than apply the increase in aggregate payments to account for the cost of non-therapy ancillary services by means of an adjustment to the nursing index, CMS should factor the adjustment into the unadjusted nursing case mix component of the rate. By including the adjustment for NTAS in the nursing rate, the Medicare cliff would begin to be smoothed out, and would also be administratively easier to implement as it eliminates the need for CMS to annually adjust the nursing index.

Second, CMS should apply an appropriate transitional quarterly budget neutrality adjustment factor that would reduce payment rates to the annual average per diem in the first quarter and increase payment rates to the annual average per diem in the second through fourth quarters. Through this process, CMS would eliminate the per diem cliff associated with the refinement without impacting overall aggregate payments for FY 2006.

Chart 1: Medicare Rate Cliff Associated With RUG Refinement



C. AHCA Concerns About SNF Industry Stability

1. SNFs In Effect Forgoing Market Basket Update In FY 2006

AHCA is concerned about the impact of the proposed rule on the financial stability of the long-term care sector, particularly as it relates to nursing homes. The proposed reduction in payments and regulatory changes in the proposed rule represent a significant cut for SNFs. Without modification, the economic impact of the proposed rule could be as destabilizing to the long term care sector as when the SNF PPS was implemented.

In the FY 2006 SNF PPS proposed rule, CMS estimates that the 3.0 percent increase in the market basket will increase payments to SNFs by approximately \$510 million in FY 2006, and that the current 20 percent add-on to the adjusted payment rates for 12 complex medical RUG categories, the 6.7 percent add-on to all 14 rehabilitation RUG categories, and the 128 percent add-on for AIDS patients, would have represented approximately \$1.4 billion in payments to SNFs if they remained in effect for all of FY 2006.

Under the proposed rule, CMS estimates that there will be no change in aggregate FY 2006 spending relative to FY 2005. Given that SNF costs increased by about 3 percent in FY 2005, this has the effect of reducing payments to SNFs by the same amount as the market basket update of 3.0 percent, or \$510 million in FY 2006 and an estimated \$750 million in FY 2007. At the facility level, the CMS proposed rule will thus have the effect of cutting average SNF per diems by approximately \$16 per day from approximately \$336 pre-refinement to \$320 post-refinement, a rather substantial reduction in payments rates.

2. Research Suggests Additional Reduction In SNF Payment In FY 2006

As noted above, AHCA is further concerned that the changes in SNF payments as presented in the proposed rule, actually reduce payments to SNFs by an estimated \$90.6 million in FY 2006, rather than the "no change in aggregate payments" asserted by CMS. This discrepancy is of particular concern. AHCA encourages CMS to undertake an appropriate review of the proposed SNF PPS and necessitate that an appropriate adjustments be made to the SNF PPS so that the negative economic impact of the refinement is not greater than that estimated.

3. Proposed Look-Back Changes Contrary To Basis Of SNF PPS

The FY 2006 economic impact estimate in the proposed rule is also predicated on the assumption that CMS will not modify the underlying basis of the SNF PPS - the recording and use of the Minimum Data Set (MDS). In the proposed rule, CMS suggests that elimination of the 14-day look-back period will help ensure the accuracy of patient classification and that patient classification to an Extensive Services RUG is not based solely on services provided prior to SNF admission.

The development of the current RUG classifications are based on time-and-motion studies that document the service times for supporting patients in particular RUG categories. The look-back provision was not established to determine that a particular service was delivered but rather to

determine whether the types of patients that entered the SNF required more intensive care. In the case of IV medications, the critical point is not that the patient is receiving IV in the SNF or received it in the hospital, but rather that the current time studies show that a patient that either received or is receiving IV treatment in the past 14-days requires more intensive nursing services. Further, elimination of the look-back period within the MDS will negatively impact quality measures and an important piece of care history that must be considered in developing appropriate care plans and in providing quality care.

4. SNF Bad Debt Issues Can Not Be Resolved With Provider Incentives

The FY 2006 economic impact estimates of the proposed rule is also predicated on the assumption that there will not be a reduction in Medicare allowable bad debt. CMS had originally raised the issue of a reduction in allowable bad debt in on February 11, 2003, in a proposed rule providing for a reduction in allowable bad debt reimbursement to all providers eligible to receive bad debt. 67 Federal Register 6682. The rule called for a graduated decline in bad debt reimbursement by 10 percent in the first year, 20 percent in the second year, and by 30 percent in all subsequent years.

CMS estimated that the financial impact to SNFs of the proposed 30 percent reduction in FY 2006 would be \$90 million. AHCA had completed its own analysis of the potential impact which ranged from \$86 million to \$357 million in 2006 depending on how many states ceased paying SNF Medicare co-payments for the dual eligibles. Indeed, approximately 80 to 90 percent of SNF bad debt relates to dual eligible beneficiaries. At the time of the issuance of the proposed rule, AHCA research showed that 21 states had already limited Medicaid payments for Medicare Part A coinsurance, and 4 states clearly were not paying anything. We believe that the number of states limiting or not paying co-payments has risen dramatically.

Despite suggestions that the reduction would increase incentives for providers to collect unpaid coinsurance payments, in the context of the SNF setting where the major part of SNF bad debt is associated with Medicare co-payments for dual eligible beneficiaries, it is clear that SNFs have little recourse to seek additional Medicaid payments of Medicare co-payments. Since limited state payment or non-payment of copayments is permissible under the Medicaid law, CMS plays an important role in ensuring that other payers are not expected to subsidize Medicare bad debt by continuing to implement regulations first developed in 1966 for Medicare reimbursement of uncollected co-payments.

5. Smoothing Out The Payment Rate Cliff

As noted above, the implementation of the amended proposed rule as currently designed would reduce average Medicare per diems by about \$16 effective January 1, 2006. Given that the dramatic reduction in rates could have an undesirable destabilizing effect for numerous providers, AHCA recommends that CMS adopt a two pronged approach to smoothing out the Medicare rate cliff. Under this approach, CMS should, first, factor the adjustment for NTAS variability into the unadjusted nursing case mix component of the rate, and second, apply an appropriate adjustment to the nursing and therapy indices to equalize per diem rates over each quarter in FY 2006.

For example, analysis by the Lewin Group estimates that the average per diem for FY 2006 will be approximately \$325, with the average per diem in the first quarter of FY 2006 of \$336 under the current RUG-44 system dropping to \$320 for the last three quarters of the year under the proposed RUG-53 system. Application of an appropriate adjustment factor would reduce payment rates to the annual average per diem in the first quarter, increase payment rates to the annual average per diem in the second through fourth quarters, and eliminate the per diem cliff associated with the refinement, all without impacting overall aggregate payments for FY 2006.

The application to the proposed adjustments factors would be consistent with the FY 2006 SNF PPS proposed rule and would apply to the current RUG-44 system for the fiscal quarter and the proposed RUGS-53 system for the last 3 quarters of the year. Analysis by the Lewin Group suggests that budget neutrality is consistent with a nursing and therapy index that would be reduced by 4.0 percent and 3.8 percent respectively during the first quarter of FY 2006, and increased by 2.35 percent and 2.45 percent respectively during the remaining quarters of FY 2006.

6. Medicare's Role In Cross-Subsidizing Medicaid

AHCA is also concerned about what impact the reduction in payment rates effective January 1, 2006 will have on already low margins among the nation's nursing homes and the effect the reduction in Medicare payments will have in cross-subsidizing low Medicaid payments. Research conducted by Friedman, Billings, Ramsey & Co. in 2004 estimated the net margin for nursing facilities at only 2.8 percent, the lowest among all other healthcare service providers³. The reduction in Medicare payment rates by approximately \$16 per day, coupled with scant increases in nursing facility Medicaid payments, will further squeeze the overall margins of nursing facilities. Preliminary estimates by the Lewin Group indicate that this reduction in payments could reduce overall total nursing facility margins by 1.5 to 2.0 percent – thereby further reducing already slim margins.

Medicare has also historically played an important role in cross-subsidizing low Medicaid payments. This cross-subsidization takes place in most healthcare settings. Losses generated by treating one category of patients are underwritten by payments generated by another category of patients. In the case of hospitals, cross-subsidization occurs across departments. By contrast, in the freestanding SNF setting the cross-subsidization occurs across government payers. Though the form of cross-subsidization is different, the operational realities are very much the same. The cross-subsidization of Medicaid by Medicare is a policy that is in place today – empirical evidence and hard data show that it is occurring. While no one would advocate that one entitlement subsidizing another is good long-term policy, it is a current necessity to ensure the adequacy and quality of patient care.

³ Kumpel, J. J., and Dewhurst, A. (2004). Skilled Nursing Facilities: The Phoenix Rises Again. Healthcare Research Report. Friedman, Billings, Ramsey, & Co. December 20, 2004.

7. Inadequacy Of The SNF Case-Mix Refinement Adjustment

In the proposed rule, CMS proposed to provide for an additional adjustment to the nursing component of the case-mix weights (which includes non-therapy ancillary services) for all RUG-53 group to better account for non-therapy ancillary variability. The additional adjustment seeks to improve the accuracy of payment allocation and account more directly for cost variations related to NTAS. In setting the size of the adjustment at 3 percent of aggregate expenditures, CMS considered the high degree of variability in NTAS costs as well as the absence of an outlier policy under the SNF PPS. 70 Federal Register 29079. As noted in the Ongoing Case Mix and SNF PPS Rate-Setting Analyses posted by CMS on its internet site on June 29, 2005, the 3 percent increase in aggregate expenditures would be implemented by an 8.85 percent across-the board increase to the nursing component of the case-mix weights.

AHCA has concerns about the adequacy of the size of the adjustment to the nursing weights to account for non-therapy ancillary services costs, as well as all other related issues. While a 3 percent adjustment in aggregate expenditures for outlier cases may be sufficient in the IRF setting, it does not appear to be sufficient in the SNF setting. In addition to being asked to cover the high cost and high degree of variability in NTAS costs, the adjustment also seeks to respond to the wide variation in resource needs of patients under the proposed RUG-53 system. 70 Federal Register 29079.

Implicitly, the adjustment also seeks to account for greater resource use within RUG categories than would have been suggested based on the time and motion studies upon which the SNF PPS system is based. Given the availability of alternative settings, nursing home populations are becoming increasingly frail and disabled. Research by both AHCA and the Lewin Group show that average activities of daily living (ADLs) of nursing home residents - including Medicare residents - have been increasing over time. While some of the variation in resource needs of this population is captured by the SNF RUG system, increasing resource needs and cost of care of residents within RUG categories is not adequately captured by the existing SNF PPS. Given that resource requirements for existing SNF populations are increasing, AHCA proposes that an additional pool of funds equivalent to 3 percent of aggregate expenditure be allocated for the wider variation in resource needs for all patients under the proposed RUG-53 system and to respond to greater resource needs within RUG categories, during the interim period until the results of new time and motion studies are available to update the nursing and therapy indices upon which the current SNF PPS is predicated. As the predictive power of the SNF PPS is weak and lacks adjustment mechanism that exist in other prospective payment systems, allocation of the interim adjustment should be reflected by appropriate increases in both the nursing and therapy weights.

II. Clinical Issues

AHCA Recommendation On The Look-Back Period For MDS Section P1a, Grace Days, And Concurrent Therapy:

- CMS should not decrease or eliminate the 14-day look-back period at MDS Section P1a
 because of the negative impact of elimination on care quality, care planning and quality
 measurement;
- CMS should not decrease or eliminate grace day periods associated with any PPS MDS
 assessments including the 5-day PPS assessment because of the negative impact of
 elimination on care quality, care planning and quality measurement;
- CMS should continue to thoroughly examine the incidence of "routine use of grace days" to identify specific areas of concern and appropriate modifications; and
- CMS should not issue additional regulations addressing concurrent therapy, given the systems already in place to ensure that concurrent therapy meets the skill level and is clinically appropriate for the given beneficiary.

A. Appropriateness of the MDS 14-Day Look-Back Period at MDS Section P1a

CMS is seeking comment on potential savings and other impacts of revising the MDS Manual instructions to include only those special care treatments and programs (MDS Section P1a) furnished to the patient since admission or readmission to the SNF. The MDS Section P1a captures special treatments, procedures and programs including chemotherapy, dialysis, IV medication, intake/output, monitoring acute medical conditions, ostomy care, oxygen therapy, radiation, suctioning, tracheostomy care, transfusions, ventilator or respirator care, alcohol drug treatment programs, Alzheimer's/dementia special care units, hospice care, pediatric care, respite care and training in skills required to return the patient to the community.

CMS expresses the view that eliminating the 14-day look-back period will help ensure the accuracy of patient classification and eliminate the number of individuals to classify as Extensive Services category based solely on services that were furnished exclusively during the period before the SNF admission. The CMS rationale for eliminating the look-back period is based on reimbursement concerns only, without regard to the impact of removing the look-back on patient assessment, transition of care, care planning and quality measurement. Removing the look-back period on MDS Section P1a would negatively impact the quality of care of the beneficiary, care planning, and quality measurement. Also, as noted in the previous section, the elimination of the look-back provision will penalize SNFs that must commit resources within the first few days of admission when patients are most unstable, typically utilize resource most intensively, and require a significant level of skilled nursing care for monitoring and treating symptoms related to their hospital stay.

MDS Section P1a is the main area on the MDS 2.0 that captures history of recent care requiring extensive services. Eliminating the 14-day look-back period would eliminate the care history that must be considered in developing appropriate care plans and in providing quality care.

1. Cancer Diagnosis and Treatment

In looking at cancer diagnosis and treatment, the elimination of the 14-day look-back would put the patient at significant risk. When patients complete either chemotherapy and/or radiation treatments that are known to have significant side effects and/or associated with post-treatment complications and that would not be suspected or monitored without the knowledge of the treatment (what type, when provided and duration), it is imperative that the history of the treatment is captured and considered in the assessment and care plan. For example, the following conditions are common following cancer treatment:

- Clotting disorders resulting from anti-coagulants prescribed for patients with indwelling groshong or port catheters used for the delivery of the chemotherapeutic agent;
- Any residual red/white blood cell count abnormalities as a result of the chemotherapy that can result in increased risk of infection or tiredness which for the elderly and disabled may be more significant since tiredness is a symptom of several other disorders requiring evaluation and treatment;.
- New studies indicate that chemotherapy may have a direct short- and long-term effect on cognition and could be very significant to patients with or suspected of having dementia and Alzheimer's Disease; and
- Specific side effects and/or complications associated with chemotherapy/radiation such as:
 - Bowel obstruction is a common side effect of the treatment of colorectal cancer.
 Caregivers need to monitor for nausea, vomiting and change in bowel/stool patterns. Clinician awareness of recent treatment is critical for early detection and appropriate treatment and particularly for patients who are unable to verbalize or communicate symptoms or who demonstrate mental incapacity; and
 - Depending on the site and dose, skin deterioration, excoriation and burns are common side effects of radiation treatments. These skin conditions can re-appear even if they are not apparent when the patient is admitted. Their occurrence in the hospital increases the risk of pressure ulcers for these patients if the SNF clinical staff are not aware of the skin compromise. Such lack of awareness can happen if the radiation treatment is eliminated in the look-back period and therefore not included in the assessment.

2. IV Medication

Fully capturing the treatment history for all P1a treatments and programs is essential to patient safety. IV medication administered in the last 14 days is most likely indicative of an acute health episode where quick acting medication was needed. Even if the IV medication is discontinued prior to the time the individual is admitted to the nursing home, the clinician needs

to monitor the patient's condition for recurring symptoms, medication side-effects and residual effects from toxicity, inflammation, infection and trauma at the IV site.

The existing MDS coding instructions already inappropriately limit coding under P1a. In August, 2003, CMS issued MDS coding changes that require clinicians not to include IVs, IV medications and blood transfusions provided during chemotherapy or dialysis for a patient who is already in a SNF stay. In the recent June 2005 update, a clarification was again made to section P1a that stated "do not code services that were provided solely in conjunction with a surgical or diagnostic procedure." Pursuant to this directive, the MDS would not contain IV medications given during a procedure like diagnostic colonoscopy but would contain IV medication data if the patient received out-patient treatment in a hospital for dopamine infusion (cardiac treatment). Thus, further adding an exclusion for IV medications administered during the 14-day look-back period further limits coding and raises serious concern about the quality and usefulness of the information captured on the MDS for the purpose of providing care.

3. Impact on Care Planning

The elimination of the 14-day look-back impacts care planning significantly and negatively. As previously stated, Section P1a is the only section of the MDS currently with a 14-day look-back period in place to capture recent history of treatments and programs. In evaluating the Resident Assessment Protocols (RAPs), no care plan triggers are found associated with MDS Section P1a. Interestingly, the absence of a trigger suggests that no recent treatment or medical program history is considered in the RAPs. This omission raises concern over the ability of the current RAPs to lead the clinician in developing care plans that are comprehensive enough to provide the care that is needed. At least the current MDS with the P1a 14-day look-back period in place, alerts the clinician to any recent treatments and programs that will require clinical follow-up and patient monitoring. To eliminate the look-back and couple that with the weakness in the current RAPs, the Resident Assessment Instrument (RAI) (MDS and RAPs) that are required by regulation, will seriously compromise the clinician's ability to provide quality care.

4. Impact on Nursing Home Quality Measures

The elimination of the 14-day look-back period also compromises the publicly reported nursing home quality measures. If the 14-day look-back period at P1a is eliminated, many patients whose condition warrants their exclusion will be calculated in three publicly reported quality measures.

For example, the post-acute measure for delirium and the chronic care measures for ADL decline and mobility decline all exclude hospice - P1ao from the calculation of the measure. This exclusion is correct because these are individuals who are near the end of life when decline is expected and their inclusion would have an inappropriate negative impact on quality measurement. However, if the 14 day look-back period is eliminated such a negative impact may occur because the absence of a 14-day look-back may result in the failure to identify individuals discharged from hospice prior to being admitted to the nursing facility.

Indeed, according to the study, Synthesis and Analysis of Medicare's Hospice Benefit, provided in March of 2000 by Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services (HHS), about 14 percent of nursing home patients are discharged from hospice alive. Another study conducted by Susan Miller, et al from Brown University in 2000, Use of Medicare's Hospice Benefit by Nursing Facility Residents, found that hospice patients who begin their hospice episode in the community and are discharged and later admitted to a nursing facility have an average length of stay of 77.9 days. This finding demonstrates that these patients remain in decline despite the cessation of hospice services. Thus, as indicated above, eliminating the 14-day look back will prevent identification of these individuals and a bias in the measurement of quality. In addition, these individuals may not exhibit other symptoms that would have excluded them from the calculation of the quality measures such as coma or the end-stage designation found at MDS Section J5c.

5. Conclusion

AHCA recommends that CMS not eliminate the 14-day look-back period at MDS Section P1a, given the negative impact on care quality, care planning and quality measurement. The proposed look-back elimination fosters health care delivered in silos – an approach, in this circumstance that is blind to the relationship between provided care, recently concluded treatments and procedures, and the individual's immediate health and well-being. Patient assessment and care planning cannot play "second fiddle" to reimbursement. When the assessment tool is also the reimbursement tool, the patient and the ability to adequately assess and care for the patient must be considered first.

B. Grace Days

CMS states that it has received recommendations to decrease or eliminate grace day periods for the 5-day PPS assessment. It invites comment on this specific recommendation as well as the option of decreasing or eliminating the grace day periods associated with all PPS MDS assessments. CMS implies that these are policy options that could enhance the accuracy of the payment system and improve quality of care, but does not explain the basis for this assertion. AHCA does not agree that decreasing or eliminating grace day periods for the 5-day PPS assessment nor decreasing or eliminating the grace day periods associated with all PPS MDS assessments is appropriate. Grace days, properly used, play an important role in providing quality care and receiving adequate reimbursement for that care.

According to the RAI Manual, p2-28, grace days are added to the Assessment Resident Date (ARD) to allow for absence/illness of the RN assessor, reassignment of the assessor, or for an unusually large number of assessments due at the same time frame. Grace days may also be used to more fully capture therapy minutes or treatments but the RAI Manual suggests that they should be used sparingly. The manual warns that routine use of grace days is subject to survey, fiscal intermediary (FI) review and Data Assessment and Verification (DAVE) program review.

AHCA agrees that grace days should be used carefully and in limited circumstances but, as indicated above, grace days, properly used, play an important role in providing quality care and

receiving adequate reimbursement for that care. Appropriate use of grace days is necessary to more fully cover treatment and minutes of therapy.

For example, a patient may refuse therapy for a day due to illness, or temperament. When delays are caused by patient temperament, the patient is transported to the therapy department and staff or staff hired to perform the service cannot do so as scheduled. If the service is not performed, the day cannot be counted for MDS purposes and as a result, the patient does not meet the 5 day/week requirement for a rehabilitation RUG. In this case, the grace days allow the flexibility of looking back during a time frame that will more accurately measure the intensity of services provided and delivered to the patient. If the grace days are removed from the 5 day assessment, the Ultra High Intensity RUGs will rarely be met. Reimbursement will be inadequate for the care ultimately being delivered to the patient.

Additionally, grace days can be warranted in relation to late in the day and weekend admissions which are not uncommon practices. In these cases, no evaluation for rehabilitative needs or actual therapy treatment can be considered at the time of admission. If rehabilitation is needed, the most that could be provided to the patient would be 4 days of service which would not produce a rehabilitation RUG. The use of the predictive Section T would produce a rehabilitation RUG but not at the actual intensity of services that would need to be provided.

If properly utilized, grace days are an important aspect of accurate MDS assessment. We disagree with decreasing or eliminating the grace day period for any PPS MDS assessments. CMS should continue to thoroughly examine the incidence of "routine use of grace days" to identify specific areas of concern and appropriate modifications.

C. Concurrent Therapy

The proposed rule solicits comments on the "most effective way to prevent the abuse of [concurrent therapy]... and to ensure that concurrent therapy is performed only in those instances where it is clinically justified." 70 Federal Register 29069, 29083 May 19, 2005. As the proposed rule notes, and AHCA agrees, there are circumstances where concurrent therapy is clinically appropriate and therefore proper as a covered service, and instances where it is not. We also believe that it is inappropriate for any entity to coerce a therapist into conducting concurrent therapy that is inconsistent with the therapist's sound clinical judgment. Conversely, concurrent therapy, administered responsibly can not only meet the complex skill level required for Medicare coverage, but also can benefit the individual patient.

Medicare has systems in place to ensure that concurrent therapy meets the skill level and is clinically appropriate for the given beneficiary. First, therapists are already required to document the level of complexity and sophistication of the services that they provide to a given beneficiary. Second, focused medical reviews by the FIs are effective in detecting and deterring the improper use of concurrent therapy. There is nothing to indicate to the contrary. Moreover, Medicare's current enforcement system is further enhanced by state laws and professional codes of ethics. Specifically, the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language and Hearing Association and the laws in many states set out a code of ethics for physical therapists, occupational therapists and speech

language pathologists and standards of practice, respectively. We believe that vigorous enforcement of these state and professional codes, along with Medicare's current guidance, should deter the inappropriate use of concurrent therapy.

We believe that further guidance or additional documentation requirements will do little to deter those who are ethically challenged. Additional regulation, however, will increase the costs to those facilities and therapists who are law abiding and provide services in the best interests of the beneficiaries, without providing additional deterrence to those few who are less than fully compliant. Therefore, we do not believe that additional regulation in this area is justified under the Paperwork Reduction Act, the Regulatory Flexibility Act, or the Unfunded Mandates Reform Act of 1995. See 44 U.S.C. §§ 3501-3520, 5 U.S.C. §§ 601-612, and 2 U.S.C. §§ 1501-1571, respectively.

III. Proposed Revision of SNF PPS Geographic Classifications:

AHCA Recommendations on the Proposed Revision of SNF PPS Geographic Classifications:

- CMS should proceed to develop and apply a SNF-specific area wage index, effective no later than FY 2007, and should immediately request the resources necessary to accomplish this;
- CMS should give SNFs the ability hospitals have to reclassify to more appropriate areas, by developing the SNF-specific area wage index required by Congress as the basis of geographic reclassification for SNFs;
- Concurrent with the development of a SNF-specific wage index, CMS should set in place the procedures for SNF geographic reclassification;
- CMS should include methodology in the SNF PPS to establish a "rural" floor for the wage index, such that, as in the case of hospitals, the area wage index applicable to any SNF that is not located in a rural area may not be less than the area wage index applicable to SNFs located in rural areas (or pseudo-rural areas in the case of all urban states); and
- If CMS takes the position that it has the authority to apply the OMB CBSA area wage designations, CMS should develop and implement the four-year phase-in as outlined by AHCA in order to allow SNFs to make appropriate adjustments in their operations, particularly those SNFs that are most dramatically affected by the proposed changes.

Discussion

As part of the notice of proposed rulemaking, CMS invites comments on proposed revisions to the SNF PPS labor market areas. Specifically, CMS is requesting comments on revised definitions for Metropolitan Statistical Areas (MSAs) using the Core-Based Statistical Areas (CBSAs) defined by the Office of Management and Budget (OMB), in the OMB Bulletin No. 03-04, and the immediate implementation of the changes in local labor market area designations.⁴

AHCA is encouraged that CMS is seeking to implement measures that would modify the definition of MSAs to make the payment system more accurately reflect SNF costs associated with local labor market conditions. However, the proposal to adopt the OMB CBSA designations fails to correct inherent deficiencies and distortions in the wage index used to adjust SNF payments to reflect local labor market conditions. The implementation of the OMB CBSA designations without addressing other outstanding issues such as deficiencies in the wage index

⁴ See June 6, 2003, Office of Management and Budget (OMB) issuance, Bulletin No. 03-04. In the bulletin, OMB announced revised definitions of Metropolitan Statistical Areas and new definitions of Metropolitan Statistical Areas and Combined Statistical Areas. A copy of the bulletin may be attained at the following Internet address: http://www.whitehouse.gov/omb/bulletins/b03-04.html

currently used in the SNF setting, the lack of methodologies in the SNF PPS for geographic reclassification, and the lack of a rural floor, will not improve the accuracy of the payment system. Instead it will inflict unnecessary unintended effects on SNF providers. Given the significant impact of the adoption of the OMB CBSA designations on certain providers, CMS should not proceed with the OMBA CBSA designations at this time.

Instead it should <u>first</u> develop and implement a SNF specific wage index that would allow the payment system to more accurately reflect differences in area wage levels and would allow SNFs to request reclassification to alternate, more appropriate local market designations. CMS should also implement provisions that would establish a "rural" floor similar to the inpatient hospital PPS to deal with budget neutrality created anomalies in the SNF PPS that reduce the wage index in certain urban area below that in rural areas, where costs tend to be lower. AHCA is eager to work with CMS to bring about needed modifications so that the SNF PPS could better reflect local labor market conditions.

AHCA is concerned that the proposed adoption of the OMB CBSA wage area designation may not only have untoward and distortionary effects, but may also assign MSAs using a tripartite classification scheme that is not permitted by the SNF PPS enabling legislation, the Balanced Budget Act of 1997 (BBA). Thus, AHCA believes that CMS' authority may be constrained by the implementing legislation that wage indices can only vary as a function of rural or urban location, and that CMS lacks the authority to include a third variant -- a micropolitan location.

However, if CMS takes the position that it has the authority to apply the OMB CBSA area wage designations, and to avoid the matter being litigated, CMS should develop and implement an appropriate multi-year phase-in plan that would allow SNFs to make appropriate adjustments in their operations, particularly for those SNFs that are most dramatically affected by the proposed changes. In addition to a phase-in of the OMB CBSA wage area designations, CMS should develop and implement a SNF-specific area wage index, establish the methodology in the SNF PPS for SNFs to request reclassification to alternate more appropriate local market areas, and establish a methodology in the SNF PPS to establish a "rural" floor for the wage index.

In conclusion, AHCA believes that CMS should not proceed with the OMB CBSA wage area designations at this time. CMS should develop the critically important changes referenced above and apply them to SNFs either before, or concurrently with, the OMB CBSA wage area designations - with an appropriate phase-in that would allow providers to transition to the new index without undue dislocation.

A. CMS Lack Of Authority to Implement OMB CBSA Designations for SNFs

AHCA is concerned that the proposed adoption of the OMB CBSA wage area designation may not only have untoward and distortionary effects, but may also assign MSAs using a tripartite classification scheme that is not permitted by the SNF PPS enabling legislation, the Balanced Budget Act of 1997 (BBA). AHCA believes that CMS' authority may be constrained by the implementing legislation, that wage indices can only vary as a function of rural or urban location and, and that CMS lacks the authority to include a third variant -- a micropolitan location.

In the notice of proposed rulemaking, CMS noted that,

[u]nder the OMB's new CBSA designations, Micropolitan Areas are essentially a third area definition consisting primarily of areas that are currently rural, but also include some or all of areas that are currently designated as urban MSAs. . . . [H]ow these areas are treated [will] have significant impacts on the calculation and application of the wage index. 70 Federal Register 29093

The proposed rule goes on to state that the "statute provides the Secretary with broad authority to use an "appropriate wage index as determined by the Secretary." 70 Federal Register 29091. The proposed rule further notes that the SNF PPS has traditionally used the same methodology for calculating wage indices as CMS has adopted in the in-patient prospective system ("IPPS") for hospitals and that IPPS has keyed its classifications to OMB issuances. Thus, according to the preamble, "OMB defined MSAs [Metropolitan Statistical Areas] around a minimum core population of 50,000, and smaller areas were 'Outside MSAs.' On June 6, 2003, the OMB announced the new CBSAs [Core-Based Statistical Area] comprised of MSAs and the new Micropolitan Areas based on Census 2000 data." 70 Federal Register 29091.

While we agree that CMS has broad authority to set wage indices for the SNF PPS, that authority is not unlimited but rather is tethered by the enabling legislation. See Chevron U.S.A. v. Natural Res. Def. Council, 467 U.S. 837. Under Chevron, a court must first determine if Congress has spoken directly to the question at issue. If Congress' intent is clear, the inquiry must end and the court "must give effect to the unambiguously expressed intent of Congress." Id. at 843. This is called a Chevron I analysis and does not involve deference to the agency. If, however, the court determines that Congress has not directly spoken to the issue and that "the statute is silent or ambiguous with respect to the specific issue," the court must ask whether the agency's interpretation is based on a "permissible construction of the statute." Id. This is called a Chevron II analysis and in the context of rulemaking the courts will defer to the agency. See Robert Wood Johnson University Hospital v. Thompson, 297 F.3d 273, 286 (3rd Cir. 2002) (upholding Secretary's application of wage index provision because "the statute is ambiguous, but ... the Secretary's interpretation is impermissible or unreasonable").

AHCA believes that the organic legislation limits the CMS's authority and that this inquiry ends with a *Chevron I* analysis.

First, the SNF PPS provision consistently recognizes, for payment purposes, only two distinct areas -- rural and urban: "The Secretary may compute and apply such averages [weighted average per diem rate] separately for facilities located in <u>urban and rural areas</u> (as defined in Section 1886(d)(2)(D))."⁵

For purposes of this subsection, the term "region" means one of the nine census divisions, comprising the fifty States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes; the term

⁵ Section 1886(d)(2)(D), which applies to IPPS, provides as follows: The Secretary shall compute an average of the standardized amounts determined under subparagraph (C) for the United States and for each region --

⁽i) for all subsection (d) hospitals located in an urban area within the United States or that region, respectively, and

⁽ii) for all subsection (d) hospitals located in a rural area within the United States or that region, respectively.

The Social Security Act (SSA) §1888(e)(4)(D)(iii). The wage index provision for SNF PPS reads as follows:

The Secretary shall adjust the portion of such per diem rate <u>attributable to wages and wage-related costs for the area in which the facility</u> is located compared to the national average of such costs using an <u>appropriate wage index as determined by the Secretary</u>. Such adjustment shall be done in a manner that does not result in aggregate payments under this subsection that are greater or less than those that would otherwise be made if such adjustment had not been made. SSA § 1888(e)(4)(G)(ii) (emphasis supplied).

While the IPPS provides the Secretary with broad discretion to assign <u>hospitals</u> to urban areas, rural areas, large urban areas, and other regions based on the nine census tracks, this type of express authority is simply not present in the SNF PPS provision which limits the Secretary to the "urban-rural" dichotomy. Indeed, Congress could have easily tied the SNF PPS and IPPS systems directly together by requiring that each shall be governed by the same types of census considerations. However, Congress chose to do otherwise and limited the SNF PPS rulemaking to two geographic areas as opposed to the more expansive authority that the agency has in implementing the IPPS.

Therefore, we would argue that the fact that the proposed rule mirrors the IPPS system does not save it. Under IPPS, the Secretary has significantly more latitude in setting wage indices that under the SNF PPS and can implement a variety of different types of wage indices that transcend the simple rural-urban dichotomy. Thus, while the use of a third area, the micropolitan area, may be justified under Section 1886(d)(2)(D), it is not justified under section 1888(e) which specifically links urban and rural to the definitions of those terms under Section 1886(d)(2)(D).

Moreover, creating three categories and then, treating those that fall into the third category (micropolitan) as if they were rurals, has all of the pernicious effects of a tripartite system, but none of its benefits. In short, using a "shadow" third category to artificially inflate the number of hospitals in rural areas is contrary to the legislative intent underlying the SNF PPS provisions.

Alhough AHCA believes that CMS may not have unrestricted authority to change MSA designations, AHCA also recognizes that CMS' purpose in proposing the adoption of the OMB CBSA designations is to better reflect local labor market conditions and adjust SNF PPS rates to account for differences in area wage levels. While the purpose is laudable, the proposal to adopt the OMB CBSA designations, as currently proposed, is at best a half measure that alters but fails

[&]quot;urban area" means an area within a Metropolitan Statistical Area (as defined by the Office of Management and Budget) or within such similar area as the Secretary has recognized under subsection (a) by regulation; the term "large urban area" means, with respect to a fiscal year, such an urban area which the Secretary determines (in the publications described in subsection (e)(5) before the fiscal year) has a population of more than 1,000,000 (as determined by the Secretary based on the most recent available population data published by the Bureau of the Census); and the term "rural area" means any area outside such an area or similar area. A hospital located in a Metropolitan Statistical Area shall be deemed to be located in the region in which the largest number of the hospitals in the same Metropolitan Statistical Area are located, or, at the option of the Secretary, the region in which the majority of the inpatient discharges (with respect to which payments are made under this title) from hospitals in the same Metropolitan Statistical Area are made.

to correct inherent deficiencies and distortions in the wage index used to adjust SNF payments to reflect local labor market conditions.

In conclusion, before proceeding with the OMBA CBSA designations, CMS should <u>first</u> develop and implement a SNF specific wage index that would allow the payment system to more accurately reflect differences in area wage levels and allow SNFs to request reclassification to alternate, more appropriate local market designations. CMS should also implement provisions that would establish a "rural" floor similar to the inpatient hospital PPS to deal with budget neutrality created anomalies in the SNF PPS. AHCA is willing to work with CMS to bring about needed modifications so that the SNF PPS could better reflect local labor market conditions.

B. The Development Of An Appropriate SNF-Specific Area Wage Index

CMS must proceed with the development and implementation of a SNF specific area wage index for FY 2007. Under Section 1888(e)(4)(G)(ii) of the Social Security Act CMS has the authority to adjust for geographic variations in labor costs by using an appropriate wage index. In the absence of an appropriate alternative, CMS has used the hospital wage data to develop a wage index for SNFs, since the inception of the SNF PPS.

The use of hospital wage data and a hospital wage index to establish a wage index for SNFs is inappropriate. As AHCA and others have commented in the past, a SNF specific area wage index is needed to improve the accuracy of SNF payments to providers to better reflect differences in local labor market conditions. The use of the hospital wage index in place of a SNF wage index fails to capture differences in the features, operations and services in those settings, and the differences in skills and activities of staff providing those services. While in some respects SNFs compete with other provider categories for staff, nurse shortages may in fact be much harder for SNFs to overcome than, for example, hospitals, which, given incentives in the system, may be fundamentally more attractive to nurses. Given these and other differences in the labor force and labor markets that hospitals and SNFs draw upon, a geographic area wage index reflecting hospital wage data is in AHCA's view not appropriate for the SNF setting.

In 1994, the Secretary had been directed to begin, not later than 1 year after the date of the enactment of the Omnibus Budget Reconciliation Act (H.R. 5252), "to collect data on employee compensation and paid hours of employment in skilled nursing facilities for the purpose of constructing a skilled nursing facility wage index adjustment to the routine service cost limits required under Section 1888(a)(4) of the Social Security Act." Congress provided this mandate 9 years ago.

However, in the SNF PPS proposed rule for FY 2002, CMS reported on its first attempt to gather data to develop a SNF-specific wage index, 66 Federal Register 23985. Specifically, CMS expressed concern about the reliability of the existing SNF data in view of what the agency considered to be significant variations in the SNF-specific wage data and the large number of SNFs that were unable to provide adequate wage and hourly data. In order to help develop a SNF-specific wage index, AHCA was and remains eager to work with CMS to make any

appropriate revisions to necessary forms, revise accompanying instructions and guidelines, and provide information to providers to answer questions during the data collection process.

Subsequently, in the FY 2002 final rule, CMS revealed that it would not dedicate the resources need to develop a SNF-specific wage index. 66 Federal Register 39563. CMS claimed that the necessary auditing would require a significant commitment of resources by CMS and its contractors -- a commitment that CMS refused to make.

There is no question that the development of a SNF-specific wage index would improve the accuracy of SNF payments, and CMS itself has acknowledged this in its FY 2004 SNF PPS final rule. 68 Federal Register 26767. AHCA urges CMS to proceed to develop and apply a SNF-specific area wage index, effective no later than FY 2007. As noted above, AHCA is eager to work with CMS and do what it can to assist CMS to develop an appropriate SNF-specific wage index that would improve the accuracy of payments to SNFs.

C. The Implementation Of A SNF Geographic Reclassification

In addition to the development of a SNF-specific wage index, CMS has the authority under Section 315 of the Benefits and Improvement Protection Act of 2000 (BIPA), to establish and use a geographic reclassification methodology, similar to the hospital methodology, to allow SNFs to request reclassification to an alternate, more appropriate area that would better reflect local labor market conditions. However, the geographic reclassification system cannot be implemented under current legislation until CMS has collected the data necessary to establish a SNF-specific wage index. Thus, CMS is not only prolonging the use of an inappropriate hospital wage index with its negative impact on the accuracy of the SNF wage adjustment, but it is also depriving SNFs of the ability, enjoyed by the hospitals, to have reclassifications to more appropriate indices. On both accounts, it is thus imperative that CMS develop a SNF-specific wage index.

D. The Implementation Of A Rural Floor For SNFs

Section 4410 of the BBA provides that for the purposes of Section 1886(d)(3)(E) of the Act, the area wage index applicable to hospitals located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in the State. In addition, CMS extended this "rural floor" policy for a 3-year trial period by imputing a pseudo rural floor to

⁶ The Medicare Geographic Classification Review Board (MGCRB) was established by Congress in 1989. Section 6003(h) of the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) (Pub. L. No. 101-239) created the panel, and set forth criteria for the MGCRB to use in issuing its decisions concerning the geographic reclassification, or redesignation, of hospitals as rural or urban for prospective payment purposes, Soc. Sec. Act §1886(d)(10). Hospitals may be reclassified from a rural area to an urban area, from a rural area to another rural area, or from an urban area to another urban area for the purpose of using the other area's standardized amount for inpatient operating costs, wage index value, or both, 42 CFR §412.230(a). Groups of hospitals may request reclassification of all PPS hospitals located in a county, as long as all of the PPS hospitals in the county or NECMA agree to the request. 42 CFR §412.252(b). Furthermore, 304(b) of BIPA (Pub. L. No 106-554), provided that a statewide entity, consisting of all PPS hospitals within a state, could apply for reclassification for a statewide wage index. 42 CFR § 412.235.

hospitals in all-urban states. 69 Federal Register 49110.⁷ In the hospital setting, this issue appears to arise two ways: first, where there exists a predominant labor market area, and providers located outside of this area must still compete for labor with providers in the predominant labor market area; and second, in settings where a downward adjustment of the wage index in an urban area leads to a wage index that is lower than the surrounding rural areas. Without a "floor" to protect those providers not located in the predominant labor market area from facing continued declines in their geographic wage index, it becomes increasing difficult for those providers to compete for labor.

In the FY 2006 SNF PPS proposed rule, CMS elects not to apply any rural floor to the SNF PPS wage index. CMS explains that consistent with past SNF policy, it treats this provision, commonly referred to as the "rural floor," as applicable to acute inpatient hospitals and not SNFs.

CMS does not explain its position, and this position on its face is not reasonable. Similar anomalies exist in the SNF PPS, whereby SNFs located in urban areas could have a wage index that is below the wage index applicable to providers located in rural areas. One such example pertains to Maryland: the Cumberland MD-WV labor index for 2003 was .7847, while the Maryland rural index was .8946. Given the dramatic difference between the wage indices in this instance, providers in the higher cost more urban area would be at a substantial disadvantage visà-vis providers in the lower cost rural area.

It is imperative that CMS apply the rural floor policy to SNFs. There is no statutory impediment to this policy. CMS has chosen to apply the hospital wage index to SNFs and can thus apply any aspect of this index to SNFs unless specifically prohibited by statute.

AHCA recommends that CMS add an appropriate methodology to the SNF PPS to establish a "rural" floor for SNF providers in affected areas and an imputed "rural" floor in all urban states. This methodology should be included in the SNF PPS immediately, irrespective of whether CMS proceeds with or delays the proposed adoption of the OMB CBSA wage area designation.

⁷ CMS writes "In this final rule, we are adopting a variation of the policy that we discussed in the May 18, 2004 proposed rule. We note first that there are similarities among the three States that are not impacted by the rural floor. Obviously, they are urban States. In addition, each of the three States has one predominant labor market area. That, in turn, forces hospitals that are not located in the predominant labor market area to compete for labor with hospitals that are located in that area. However, because there is no "floor" to protect those hospitals not located in the predominant labor market area from facing continued declines in their wage index, it becomes increasingly difficult for those hospitals to continue to compete for labor. In the BBA, Congress spoke of an "anomaly" in States where hospitals located in urban areas had a wage index that was below the wage index applicable for hospitals located in rural areas. (See H.R. Rep. No. 149, 105th Cong., 1st Sess. At 1305.) We think it is also an anomaly that hospitals in all-urban States with predominant labor market areas do not have any type of protection, or "floor," from declines in their wage index. Therefore, we are adopting the logic similar to that articulated by Congress in the BBA and are adopting an imputed rural policy for a 3-year period." 69 Federal Register 49110.

E. OMB CBSA based Wage Index Transition Period Needed

1. Wage Index Changes Have Significant Impact on Selected SNFs

In the SNF PPS proposed rule, CMS argues that it is not appropriate or necessary to proposes a transition to the proposed new CBSA-based labor market area for the SNF PPS wage index adjustment, and that the potential benefit of a hold harmless policy for an extremely small number of providers would be outweighed by the resulting decrease in payment rates for all providers. 70 Federal Register 29095. We disagree. Our analysis indicates that numerous providers are negatively affected by the change, particularly those located in rural areas and in certain states.

Analysis by AHCA using data in the addendum to the proposed rule, 2005 Online Survey and Certification Reporting System (OSCAR) nursing facility data, and 2002 SNF standard analytical file (SAF) claims data shows that providers in certain CBSAs, particularly rural CBSAs, and particularly those in rural CBSAs that were previously assigned to urban MSAs, will in many cases be dramatically harmed by the change in the wage index under the proposed OMB CBSA designations compared to the OMB MSA designations.

As noted in the proposed rule, the new CBSA designations recognize 49 new (urban) MSAs and 565 new Micropolitan areas, and revise the composition of many of the existing (urban) MSAs. Under the new CBSA designations 288 new MSAs were established, 41 MSAs were reclassified as Micropolitan areas, and 5 MSAs were reclassified as rural (Carter County, KY; St. James Parish, LA; Kane County, UT; Culpepper County, VA; and King George County, VA). 70 Federal Register 29091.

Overall, about 42.0 percent of counties experience a decline in their wage index, while 35.6 percent experience an increase. Rural counties are more severely impacted, with 51.1 percent experiencing a reduction in their wage index, while 34.9 percent see an increase. Five counties (Kane County, UT; Culpeper County, VA; King George County, VA; Henderson County, TX; and Mohave County, NM) are particularly negatively impacted. The wage index in these five counties drop by more the 20 percent under the proposed OMB CBSA designations compared to the OMB MSA designations.

The impact of the change in MSA designations on SNFs is also dramatic. Research by AHCA has found that 38.1 percent of facilities will experience a reduction in their wage index, while 28.8 percent will see an increase. Rural facilities in particular will be affected negatively, with 56.5 percent of facilities seeing a reduction in their wage index, while only about 32.3 percent would see an increase. Overall, nearly 600 providers will see a reduction in the wage index for their county under the CBSA designations by more than 5 percent, and about 700 providers will see an increase in the wage index for their county of over 5 percent.

The impact will also be felt dramatically in a number of states. Forty-eight percent of facilities in Idaho will experience a reduction in their wage index by more than 10 percent. In addition, 40 percent of facilities in Georgia, 63 percent of facilities in New Hampshire, 23 percent of facilities in Nevada, 16 percent of facilities in Utah, and 11 percent of facilities in South Carolina will experience a reduction in their wage index by more than 5 percent. In Georgia, Idaho, Nevada,

and Utah, the bulk of the facilities experiencing these substantial reductions in the wage index are located in rural areas.

In terms of Medicare patient day weighted average per diems (pre- and post- October 1, 2005), analysis by AHCA using 2002 SNF SAF claims data shows that the impact of the change in MSA designation appears relatively small at an aggregated level. Average per diems increased in rural areas by 26¢ to \$ 304.83, fell in urban areas by 30¢ to \$347.87, fell among freestanding facilities by 20¢ to \$339.37, and fell among hospital-based facilities by 14¢ to \$338.04. For particular states however, the impact is substantial. The change in MSA designation leads to an estimated reduction in average payments of \$15.08 per day for New Hampshire facilities and \$8.25 for facilities located in Idaho. Facilities in Arizona and Virginia experience a reduction in estimated average per diems of over \$3 per day, while facilities in New York, Rhode Island, and West Virginia see their estimated per diems reduced by over \$2 per day on average.

Though facilities in a number of states see a substantial increase in average per diems under the OMB CBSA designations (e.g. \$6.78 per day in New Jersey and \$4.16 per day in Nevada), given the dramatic and significant change in the wage index on a number of providers in certain states, particularly those located in rural areas, some type of phase in policy is necessary to mitigate the impact of dramatic changes in the wage index.

2. Wage Index Transitioning Proposal

Given that the adoption of the CBSA designations and application of a SNF-specific wage index would together cause dramatic changes in the wage index for SNFs, CMS should consider making both changes at the same time, and incorporating a multi-year phase-in approach to allow SNFs to transition without incurring significant dislocation and disruption in operations.

AHCA proposes an implementation policy be developed that would phase-in the wage index changes for all facilities. AHCA further proposes that the phase-in be conducted over a four year period to allow facilities to transition to the new system without significant dislocation. Under the AHCA proposal (a variant of option 1 considered by CMS in the proposed rule), the wage index for each provider would consist of a blend of the MSA-based wage index and the CBSA-based wage index. Under the AHCA proposal the blended MSA:CBSA based wage index would be 75 percent: 25 percent in FY 2006, 50 percent: 50 percent in FY 2007, 25 percent: 75 percent in FY 2008, and 0 percent: 100 percent in FY 2009.

IV. The SNF Market Basket

AHCA Recommendations on the SNF Market Basket:

- CMS should base the weights used in calculating the market basket update on the most up to date cost data available;
- CMS should revise and reweight the SNF market basket with greater frequency on the same schedule as the hospital market basket;
- CMS should complete the Congressionally-mandated study on how frequently the hospital market basket should be updated, and update the SNF market basket weights with the same frequency using submitted cost report data;
- CMS should evaluate other options for measuring changes in the price of wages and salaries for SNFs. Specifically, CMS should engage in a data collection effort aimed at collecting SNF-specific labor data for the purposes of creating a price proxy for labor costs in SNF; and
- CMS should study the effect of adding a separate weight for professional liability costs. CMS should work with the SNF industry to determine how the weight should be calculated, given the various financing arrangements SNFs have, and to develop an appropriate price index.

Discussion

AHCA has urged CMS to engage in a broad based thorough review of the SNF market basket that would include an analysis of all the weight and price proxy components of the current SNF market basket. To date this process had not occurred, and our concerns remain. We take this opportunity to reiterate our primary concerns with the current market basket that have considerable impact on the proposed update for FY 2006.

First, outdated weights understate cost increases. The weights used in calculating the market basket update were derived from 1997 data. Since then, changes in medical practice, SNF operations, and patient acuity have led to higher than measured increases in costs. For example, in the current formula for the market basket, prescription drugs represent approximately 3 percent of total SNF costs. By contrast, data published in Health Care Finance Review, indicate that pharmacy accounted for 13.6 percent of SNF charges in 2001. Given such substantial differences between the cost component of the market basket formula and actual SNF costs, CMS should immediately either review, revise, recalibrate, and make corrections to the market basket, or initiate a study to do so. Further, the market basket should be revised and reweighted with greater frequency — on the same schedule as the hospital market basket.

⁸ Health Care Finance Review. (2005) Medicare and Medicaid Statistical Supplement, 2003. Table 42.

Secondly, the price index used to measure changes in the wages of SNF workers, the Employment Cost Index (ECI), is a broad measure the nursing home industry wage changes, but is not specific to SNFs. There is evidence that wages in SNFs are growing faster than in the industry as a whole. CMS should use a SNF-specific wage price index calculated from data gathered from Medicare-participating facilities.

Third, the current SNF market basket does not contain a measure for the price change of purchasing professional liability insurance or of self-insuring, which is a result of CMS's use of old data and infrequent reweighting. CMS should study the effect of adding a separate weight for professional liability costs and should work with the SNF industry to determine how the weight should be calculated, given the various financing arrangements SNFs have, and to develop an appropriate price index.

A. CMS Should Reweight the Market Basket More Frequently

1997 cost reports are the primary source of the weights, by which changes in the prices of items SNFs purchase are multiplied each year to calculate the market basket update.⁹

However, since 1997, SNFs have undertaken major changes in their operations, such as implementation of the PPS and adopting new technologies. CMS acknowledges these changes in the proposed rule, stating "it became clear that the introduction of the SNF PPS and SNF consolidated billing had caused changes in facility practice patterns and billing. Some of these changes could also have been related to the use of a national database and to changing industry practices..." 70 Federal Register 29075. In addition, SNFs have been responding to marketplace changes such as self-funding for professional liability. The assignment of weights within the market basket does not reflect these changes.

It is imperative for the market basket to be reweighted on a regular basis to ensure validity (the market basket accurately reflects the type and level of expenditures in SNF) and accuracy (the impact of price changes of inputs used in calculating the update actually reflect those inputs' relative importance).

With the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Congress instructed CMS to study the frequency with which a market basket should be updated in order to be most accurate. Section 404 of the statute requires CMS to reweight the inpatient hospital market basket immediately and to establish a set frequency for revising and reweighting the market basket. The statute instructs CMS to publish an explanation of the reasons the agency choses that frequency. It is very important that CMS undertake this study, because the current frequency with which the market baskets are reweighted appears ad hoc and due to the availability of outside data sources rather than based on considerations of mathematical accuracy. Even though CMS has been charged with studying the inpatient market

⁹ Other data sources are the Bureau of the Census' 1997 Business Expenditures Survey and Bureau of Economic Analysis' 1997 Annual Input-Output tables. See 66 Federal Register 39582, July 31, 2001.

basket, the results will likely be applicable to the SNF market basket since many of the inputs and their weights are similar.

We urge CMS to complete the study, mandated by Section 404 of the MMA, on the appropriate frequency for updating the hospital market basket. We recommend that CMS update the SNF market basket weights with the same frequency as that determined by the study, using submitted cost report data. We believe that this will help to improve the validity of the SNF market basket methodology and the increase the accuracy of the market basket updates.

B. CMS Should Use a Different Price Index for SNF Wages

Our second major concern with the SNF market basket as currently conceived is the use of the Employment Cost Index for Private Nursing Homes (ECI), the price index used to calculate wage level changes for nursing home employees. AHCA objects to the fact that the price proxy includes wage price data for entities which are not SNFs and which do not receive payments under the Medicare program. SNF payment levels are being based on wage changes in non-SNF homes.

The ECI measures wage changes across a large, and disparate, group of facilities that the Bureau of Labor Statistics (BLS) lumps together as nursing homes, but which have little resemblance to the operations and patient populations of SNFs. The BLS ECI for Private Nursing Homes contains wage data for:

- Nursing facilities, (including skilled nursing facilities along with other facilities that
 would not qualify as Medicare SNFs including facilities which provide skilled care, such
 as long-term care services, but not post-acute care.)
- Intermediate care facilities and mental retardation facilities,
- Community care homes, and
- Other homes, such as personal and domiciliary care homes.

Common sense suggests that the different facilities listed above would employ a distinct mix of workers (meaning they have a different occupational mix). For example, SNFs handle patients discharged from hospitals, needing constant nursing care, rehabilitation, and other skilled nursing services. It is unlikely that the other subcategory facilities would provide that kind of care and thus would not employ the same kind and number of skilled medical workers.

It is unlikely that the ECI is reflective of price changes in SNFs because BLS data show that SNFs employ more skilled medical staff than other types of nursing facilities and that overall, the wages of medical staff are growing faster than the wages of other staff. SNFs employ about twice as many registered nurses, licensed professional nurses, and nurse aides (as a percent of total workers) as other nursing facilities, according to the Occupational Employment Statistics survey (OES).¹⁰

¹⁰ Occupational Employment Statistics Survey from 2002-2004. These surveys show that 58% of all staff members in the most skilled nursing facility category are RNs, LPNs, or CNAs. The next highest percent for any category of nursing facility is 30%. The lowest acuity category of nursing homes employs few RNs, LPNs and CNAs (less than 5% of their staff).

Table 1: 2003 Occupational Mix, by Facility Subcategory, OES

	Nursing Facilities 11	Intermediate Care Facilities	Community Care Facilities	Other Care Facilities	
RNs	7.73%	2.06%	3.94%	1.29%	
LPNs	11.28%	2.21%	5.56%	0.83%	
Nurse Aides	37.93%	6.45%	20.08%	1.64%	
All Health Workers**	64.45%	34.29%	45.84%	13.29%	

The wages of the most prevalent medical staff in SNFs are growing more quickly than for other workers in nursing homes according to BLS OES data. From 2001-2004, the wages of RNs, LPNs and CNAs have outpaced those of other nursing facility workers (from 3-4% wage price growth for nurses versus 2% for all workers). In addition, the wages in skilled facilities for the same types of workers have grown faster than in other settings. For example, wage price growth for RNs was 4.2% in 2003 in SNFs, and only 3.6% in other less skilled nursing facilities (see Table 2 below).

Table 2: Wage Growth from 2002 to 2003, OES data

	Nursing Facilities	Other Facilities	All Facilities	
RNs	4.2%	3.6%	4.0%	
LPNs	4.6%	3.6%	4.4%	
Nurse Aides	3.4%	1.9%	3.1%	
All Workers	3.3%	1.8%	2.6%	

As the table below shows, the OES data for nursing facilities, the category that includes the SNFs, show that wage changes in nursing facilities more closely resembled changes in the Hospital ECI than the ECI for Private Nursing Homes last year, indicating that the wage change profile of nursing facilities more closely resembles that of hospitals than it does of all the facilities included in the nursing home ECI.¹²

Table 3: Change in Wages from 2003 to 2004 across Sites of Care

Hospital ECI	Nursing Home ECI	Nursing Facility OES
3.5%	2.7%	3.3%

In sum, it is clear that wage growth in SNFs does not mirror wage growth in other types of nursing facilities for two reasons: SNFs employ more medical workers, whose wages are

¹¹ The OES survey does not report number of workers or wage data separately for Medicare-certified SNFs; they are lumped in with the more broad "nursing facility category." It is therefore impossible to tell whether even this category does not represent SNF wage increases.

¹² The percent change in the ECI index value is for March 2003 to March 2004; the OES data are from May 2003 to May 2004. The ECI numbers were accessed June 10, 2005, at: http://www.bls.gov/news.release/eci.t06.htm

growing faster than non-medical workers; and the wages of the same types of medical workers are growing faster in SNFs than in other facilities. The ECI for Private Nursing Homes is lower than an ECI specific to SNFs would be, and will continue to be inaccurate as long as the ECI contains wage data from facilities which do not resemble SNFs in occupational mix.

Because the wages weight represents greater than 50% of the market basket, an accurate measure of changes in wage prices is of extreme importance. The current ECI has been an inaccurate measure of wage changes in SNFs for the past 4 years, according to OES data, and will likely remain inaccurate as long as it continues to measure wages across this disparate industry.

We strongly recommend that CMS staff evaluate other options than the ECI for measuring changes in the price of wages and salaries for SNFs. Specifically, we believe CMS should engage in a data collection effort aimed at collecting SNF-specific labor data for the purposes of creating a price proxy for labor costs in SNFs.

C. CMS Should Study The Effect Of Adding A Separate Weight For Professional Liability Costs

The current SNF market basket does not contain a measure for the price change of purchasing professional liability insurance or of self-insuring, which is a result of CMS's use of old data and infrequent reweighting. The last time the market basket was revised, in 2001 using 1997 cost report data, CMS decided not to include a liability insurance input because it lacked sufficient data to accurately determine what insurance costs SNFs to purchase. The professional liability insurance market has been volatile in the past several years, and the large cost increases SNFs have faced in purchasing liability insurance or reinsurance (when self-insuring for professional liability costs) have been well documented. For example, a study by Aon Risk Consultants found that nursing home insurance liability insurance premiums have increased substantially each year over the past five years (see Table below). Because there is no weight for professional liability costs and therefore no index to measure price changes for that weight, the current market basket does not capture these cost increases.

	2001	2002	2003	2004
Median Increase over Prior Year's Premium ¹⁴	74%	82%	25%	13%
Average Increase over Prior Year's Premium	131%	143%	51%	18%

CMS should study the effect of adding a separate weight for professional liability costs. CMS should work with the SNF industry to determine how the weight should be calculated, given the various financing arrangements SNFs have, and to develop an appropriate price index.

45

¹³ AON Risk Consultants, "Long Term Care: General Liability and Professional Liability Benchmark Analysis." March 21, 2005.

¹⁴ Table adapted from AON Risk Consultant report, page 58.

V. Consolidated Billing Comments

AHCA Recommendations on Consolidated Billing:

- CMS should exclude from the SNF PPS consolidated billing certain items and services qualified for exclusion under the BBRA criteria as recommended by AHCA. In addition, they were not part of the 1995 base year costs and were not on the original BBRA list because appropriate information was not available at the time, or the items are new and their wide-spread use post-dates BBRA, or Congress inadvertently failed to include them; and
- CMS should adapt its policy on consolidated billing exclusions to encompass changes in medical practices.

Discussion

CMS invites public comment in identifying codes for further exclusions from PPS consolidated billing of services within four categories specified by Section 103 of the BBRA: chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices. CMS also believes that, given the related report language of the BBRA legislation, the services must be characterized by high cost and low probability in the SNF setting and must represent recent medical advances. AHCA recommendations provided below meet both of these criteria.

In addition, AHCA takes this opportunity to recommend the exclusion of certain other items and services and a change in the site of service policy that permits the unbundling of excluded services only if those services are provided in a hospital.

A. Recommended Drug Exclusions

In Section 103 of the BBRA, Congress excluded from the SNF PPS stem for skilled nursing facilities numerous chemotherapeutic items, as identified by their respective "J Codes," as well as numerous chemotherapy administration services, also as identified by their respective HCPCS codes. In both instances, Congress explicitly recognized that items "may have been inadvertently excluded from the [exclusion] list[,]" (H.R. Conf. Rep. 479, 106 Cong., 1st Sess. 854 (1999))and therefore, BBRA authorized the Secretary to identify "any additional chemotherapy items" and "any additional chemotherapy administration services" to be excluded from PPS. BBRA § 103(a)(2), amending the Social Security Act by adding new paragraphs at 1888(e)(2)(A)(iii)(I) and (II), codified at 42 U.S.C. § 1395yy(e)(2)(A)(iii)(I) and (II).

The BBRA, however, provided the Secretary no guidance in expanding the list of items or services to be excluded in the future from the PPS. The Conference Report accompanying the legislation, however, noted that the specific chemotherapy items were excluded from PPS because "these drugs are not typically administered in a SNF, or are exceptionally expensive, or are given as infusions, thus requiring special staff expertise to administer." H. Conf. Rep. 479, 106th Cong., 1st Sess. 854 (1999). In a subsequent rulemaking, the Secretary, building on the

report language, indicated that items or services that were of the same type as described in one of the four categories in Section 103, including chemotherapy and chemotherapy services, could qualify for exclusion from SNF PPS if (i) "they also meet the same standards of high cost and [ii] low probability [of being used] in the SNF setting." 70 Federal Register 29098 quoting 65 Federal Register 46791.

We believe that certain chemotherapies that now otherwise qualify for exclusion under the criteria noted above were not part of the 1995 base year costs and were not on the original BBRA list because appropriate information was not available at the time, or the items are new and their wide-spread use post-dates BBRA, or Congress inadvertently failed to include them. These drugs are chemotherapy drugs, or cancer chemotherapeutic agents or adjuncts to such agents and are high cost, and have low probability of use in the SNF setting. In short, the drugs listed in Tables 2-6, are the types of items that Congress intended to exclude from SNF-PPS and would have included on the exclusion lists had the information been available at the time. AHCA therefore proposes that CMS excludes the following drugs:

- Certain chemotherapy drugs that meet the high-cost and low probability criteria (Table 2);
- A class of anti-cancer drugs known as antineoplastics. Unlike traditional chemotherapies, these new chemotherapeutic agents are not cytotoxic. Nonetheless they are high-cost and infrequently used in the SNF setting (Table 3);
- Drugs that are traditionally used in combination with chemotherapy, such as antiemetics and supportive care drugs. Those that listed in Tables 4 and 5, are high-cost and low probability drugs; and
- Oral chemotherapeutic agents currently in the Medicare Replacement Drug
 Demonstration Project. These drugs are part of the demonstration project precisely
 because they are new, very expensive, and although life-saving, but not covered under
 Part B (although they may be covered under Part D beginning in 2006). They have
 extraordinarily low utilization in a SNF setting (Table 6).

1. Addition of C Codes to Currently Excluded Drugs - Table 1

First, we ask CMS to correct a cause of current confusion regarding drugs already excluded. Some chemotherapy drugs have 2 HCPCS assigned - a "J" code and a "C" code. Hospital outpatient departments are mandated to use "C" codes when billing Medicare for some chemotherapy drugs under the hospital outpatient prospective payment system. However, the "C" codes are not represented in the excluded chemotherapy drug listing. This has caused confusion. Medicare is rejecting hospital bills for payment and SNFs are being asked to pay for these high cost drugs when in fact, the "J" code for the same drug and dosage is excluded. Below is a listing of the already excluded "J" code chemotherapy drugs with their corresponding "C" codes. CMS should add the following hospital outpatient "C" codes to the excluded chemotherapy list.¹⁵

¹⁵ CMS Manual System, Pub. 100-04, Medicare Claims Processing, Transmittal 360, November 5, 2004, Major Category III, A., Additional Excluded Services Rendered by Certified Providers, Chemotherapy.

Table 1: "C" HCPCS and Corresponding "J" Codes

HCPCS "C"	HCPCS	Description	
	 		
C9417	J9040	Bleomycin sulfate injection	
C9418	J9060	Cisplatin 10 MG injection	
C9419	J9065	Inj cladribine per 1 MG	
C9420	J9070	Cyclophosphamide 100 MG	
		inj	
C9421	J9093	Cyclophosphamide	
		lyophilized	
C9422	J9100	Cytarabine hcl 100 MG inj	
C9423	J9130	Dacarbazine 100 mg inj	
C9424	J9150	Daunorubicin	
C9425	J9181	Etoposide 10 MG inj	
C9426	J9200	Floxuridine injection	
C9427	J9208	Ifosfomide injection	
C9429	J9211	Idarubicin hel injection	
C9431	J9265	Paclitaxel injection	
C9432	J9280	Mitomycin 5 MG inj	

2. CMS Should Exclude the Chemotherapy Drugs In Table 2

The following chemotherapy codes have not been excluded. CMS should add these chemotherapy drugs, indicated by code below, to the excluded chemotherapy list because they meet the criteria for high cost and low probability.¹⁶

¹⁶ These drugs should be added to CMS Manual System, Pub. 100-04, Medicare Claims Processing, Transmittal 360, November 5, 2004, Major Category III, A., Additional Excluded Services Rendered by Certified Providers, Chemotherapy.

Table 2: Non-Excluded "J9" Chemotherapy Agents

HCPCS "J"	HCPCS "C"	Descriptor	Dosage	Pricing*	Example regimen	Example # Doses per month	Monthly ASP Pricing
J9031		Bcg live intravesical vac Bacillus Calmette & Guerin	I EA	113.57	I dose diluted in 50ml NS weekly x 6 weeks then every 3 months thereafter	4	\$454
J9035	C9439	Bevacizumab injection	10 MG	57.08	350 mg every 14 days	2	\$3,630
J9098	-	Cytarabine liposome	10 MG	312.80	50 mg every 14 days	2	\$3,316
J9165		Diethylstilbestrol injection	250 MG	12.14	500 mg daily for 5 days	2	\$121
J9180		Epirubicin Hydrochloride	50MG	N/A	100-120mg/ml 3-4week cycle	28	N/A
J9190		Fluorouracil injection	500 MG	1.41	12mg/kg/d on days 1-4 non on day 5 then 6mg/kg on days 6,8 10 12 maintenance max 1g/week	4	\$49
J9202		Goserelin acetate implant	3.6 MG	185.20	3.6 mg daily every 28 days	ī	\$185
J9209	C9428	Mesna injection	200 MG	12.98	400 mg every 6 hours for 5 days with ifosfamide	20	\$519
J9213		Interferon alfa-2a inj	3 MIL UNITS	32.03	3 million IU daily for 16- 24 weeks	30	\$961
J9214		Interferon alfa-2b	I MILLION UNITS	13.26	2 million IU 3 times weekly	12	\$318
J9215		Interferon alfa-n3 inj	250000 IU	8.60	For venereal warts N/A	N/A	N/A
J9216	1	Interferon gamma 1-b inj	3000000 UNITS		1 million units/m2; 3 times per week	12	\$2,287
J9217		Leuprolide acetate /7.5 MG	7.5 MG	229.85	7.5mg monthly	1	\$230
J9218	C9430	Leuprolide acetate/ Per IMG	PER 1 MG	10.76	once daily	30	\$323
J9219		Leuprolide acetate implant (Viadur)	65 MG	2,314.14	65mg every 12 months	1	\$193
J9260		Methotrexate sodium inj	50 MG	3.84	30-40mg/m2/week	4	\$27

^{*}Pricing was obtained from CMS Drug files and is based upon payment allowance limits subject to average sales price (ASP) methodology and is based on July 2005 ASP data.

APC Status Indicator legend: B = not paid under outpatient PPS; G = drug/biological; K = Paid under OPPS separate payment, not bundled; N = bundled.

3. CMS Should Exclude The Drugs Provided Used In The Treatment of Cancer - Tables 3,4 And 5

The following is a list of drugs used in the treatment of cancer. These non-excluded drugs are used for the treatment of cancer patients and include antineoplastics, antiemetics and supportive care drugs. The antineoplastic drugs included do not have traditional cytotoxic properties but are drugs that target cancer cells at various stages of reproduction and proliferation. Supportive medications maintain blood cells, rescue healthy cells from toxic effects of antineoplastic drugs, and counteract the effects of cancer disease processes that spill over to other, nonmalignant organ systems (example: zoledronic acid to treat bone lesions affected by solid tumors). The antiemetics listed are those high-cost drugs used to treat the extreme nausea caused by chemotherapy and not general antiemetics used for other types of nausea. These drugs represent standards of care in oncology practice and are considered part of the chemotherapy regimen by oncologists.

These drugs meet the criteria of high cost and low probability. Most drugs listed below must be used in conjunction with chemotherapy due to the negative medical side effects of the chemotherapy drugs. To exclude chemotherapy from consolidated billing without excluding the drugs and biologicals needed in conjunction with this treatment is to place a financial burden on SNFs, as their costs far exceed the payment received under the PPS. Additionally, hospital outpatient departments are paid extra for these drugs and biologicals, since many are given a separate ambulatory payment classification (APC). In essence, these drugs and biologicals are unbundled for hospitals, but bundled for SNFs. These drugs are administered by injection: intravenously, intramuscularly or subcutaneously.

Table 3: Non-Excluded Antineoplastic Chemotherapy Drugs

"J"	HCPCS "C"	•	Dosage	Pricing*	regimen	Example # Doses per month	Monthly ASP Pricing
J1000		Estradiol cypionate	5MG		30 mg every 1-2 weeks	3	\$91
J1051	-	Medroxyprogesterone inj	50 MG		400 mg weekly	4	\$158
J1380		Estradiol valerate 10 MG inj	10 MG		30 mg every 1-2 weeks	4	\$137
J1390		Estradiol valerate 20 MG	20 MG	14.74	30 mg every 1-2 weeks	4	\$88
J1410		Inj estrogen conjugate 25 MG	25 MG		25 mg one time, may repeat	2	\$113
J1950		Leuprolide acetate /3,75 MG	3.75 MG	433.73	3.75 mg monthly	1	\$434
J3305		Inj trimetrexate glucoronate	25 MG	137.30	25 mg daily x 5 days	5	\$687
J8510		Oral busulfan	2 MG		70 mg every 6 hours x 16 doses	16	\$1,087
J8520		Capecitabine, oral, 150 mg	150 MG		1500 mg twice daily for 14 days	28	\$906
J9031	C9416	Bcg live intravesical vac Bacillus Calmette & Guerin	I EA		l vial weekly for 6 weeks	4	\$502
J9035		Bevacizumab injection	10 MG	57.08	350 mg every 14 days	2	\$3,630
J9098		Cytarabine liposome	10 MG	312.80	50 mg every 14 days	2	\$3,316
J9165	C9439	Diethylstilbestrol injection	250 MG	1	500 mg daily for 5 days	2	\$121
J9202		Goserelin acetate implant	3.6 MG	192.68	3.6 mg daily every 28 days	i	\$204
J9212		Interferon alfacon-1	1 MCG		9mcg 3 x / wk x 24 wks	12	\$411
J9213		Interferon alfa-2a inj	3 MIL UNITS		3 million IU daily for 16-24 weeks	30	\$935
J9214		Interferon alfa-2b	I MIL UNITS		2 million IU 3 times weekly	12	\$312
J9216		Interferon gamma 1-b inj	3000000 UNITS	292.24	0.1 mg 3 x / wk every other week	6	\$1,635
J9217			7.5 MG		once monthly	1	\$227
J9218	•	•	PER 1 MG	10.76	once daily	30	\$323
J9219		Leuprolide acetate implant (Viadur)	65 MG		65mg every 12 months	1	\$196
J9260		Methotrexate sodium inj	50 MG	2.66	30-40mg/m2/week	4	\$19

^{*}Typical price calculated as one month/one treatment at 106% average sales price (ASP) as obtained from payment allowance limits according to CMS Drug files (July 2005 ASP data).

Table 4: Non-Excluded Chemotherapy Related Antiemetic Agents

HCPCS "J"	HCPCS "C"	Descriptor	Dosage	Pricing*	Example regimen	Example # Doses per month	Monthly ASP Pricing
J1260		Dolasetron mesylate	10 MG	6.32	100 mg PO weekly	4	\$253
J1626		Granisetron HCl injection	100 MCG		70 mcg daily with chemotherapy	5	\$36*
J2405		Ondansetron hel injection	I MG	1	32 mg daily with chemotherapy	5	\$591
J2469		Palonosetron HCl (Aloxi)	25 MCG		25mcg 30 minutes before chemotherapy	12	\$213
		Aprepitant (oral)			125 mg once, then 80 mg once daily x 2 per cycle	1 (125mg) and 2 (80mg)	\$116 and \$149

^{*}Typical price calculated as one month/one treatment at 106% average sales price (ASP) as obtained from payment allowance limits according to CMS Drug files (July 2005 ASP data).

Table 5: Non-Excluded Chemotherapy Related Supportive Agents

"J"	HCPCS "C"			Pricing*	Example regimen	Example # Doses per month	Monthly ASP Pricing
J0207		Amifostine	500 MG		1500mg days 1,8 every 21 days	3	\$3,856
J1190	C9410	Dexrazoxane HCl injection	250 MG	209.70	480 mg weekly	4	\$1,610*
J1436		Etidronate disodium in	300 MG	71.41	7.5 mg daily for 3 days	3	\$340
J1440		Filgrastim 300 mcg injection	300 MCG	175.26	300 mcg daily	30	\$5,258
J1441		Filgrastim 480 mcg injection	480 MCG	277.02	480 mcg daily	30	\$8,311
J1710		Hydrocortisone sodium ph inj	50 MG	4.69	100 mg twice daily	60	\$158
J2320		Nandrolone decanoate 50 MG	50 MG	3.40	50-100mg/week	4	\$14
J2321		Nandrolone decanoate 100 MG	100 MG	6.72	50-100mg/week	4	\$27
J2322		Nandrolone decanoate 200 MG	200 MG	13.73	50-100mg/week	4	\$29
J2355		Oprelvekin injection	5 MG	245.11	3.5 mg daily	30	\$7353*
J2430	C9411	Pamidronate disodium /30 MG	30 MG	50.40	90 mg monthly	1	\$50
J2505		Pegfilgrastim 6mg	6 MG		6 mg once per chemotherapy cycle	3	\$6,263
J2820		Sargramostim injection	50 MCG		350 mcg daily x 3 per cycle	9	\$1,442
J3487		Zoledronic acid	1 MG	198.50	4 mg every 3-4 weeks	1	\$198
J9209		Mesna injection	200 MG		400 mg every 6 hours for 5 days with ifosfamide	20	\$519
Q0137		Non esrd epoetin alpha inj	1000 UNITS		300 units/kg 3 times a week	12	\$700

^{*}Typical price calculated as one month/one treatment at 106% average sales price (ASP) as obtained from payment allowance limits according to CMS Drug files (July 2005 ASP data).

3. CMS Should Exclude The Drugs Currently Utilized In the Medicare Replacement Drug Demonstration Project – Table 6

The following are a list of non-excluded drugs currently in the Medicare Replacement Drug Demonstration Project. These drugs are in this project because they are new, in oral dosage form, very expensive and considered to be life saving chemotherapy drugs, but are non-covered. The demonstration project has made drug coverage available in advance to 25,000 cancer patients. They will be available to all Medicare beneficiaries in January 2006. These drugs have the potential of replacing some of the currently excluded chemotherapy drugs. In fact, many chemotherapy regimens have focused on orally administered cancer drugs because they provide

the benefit of allowing patients to be treated in the comfort of their own homes and without incurring costly hospital stays or the dangers of nosocomial infections inherent with intravenously delivered drugs. Unless these oral agents are also excluded, SNFs will be responsible for payment of these high cost cancer drugs. These drugs meet the test of high cost and low probability.

Table 6 - Oral Chemotherapy Agents

HCPCS	Generic	Adult Dose	Unit/Pkg	Price/Pkg*	Price/Month
	Altretamine	100mg 4 times daily x 14 days	50 mg cap 100 caps	\$1,021	\$1,145
S0170	Anastrozole	1 mg daily	Img tab	\$219	\$219
	Bexarotene	300 mg/m2 once daily	75 mg cap 90 caps	\$1,781	\$3,583
	Erlotinib HCI	Used for titrating doses	25 mg tab 30 tabs	\$730	Depends on Titration up to \$2,380
	Erlotinib HCI	Used for titrating doses	100 mg tab 30 tabs	\$2,084	Depends on Titration up to \$2,380
	Erlotinib HCI	Starting: 150 mg daily	150 mg tab 30 tabs	\$2,380	\$2,380
S0156	Exemestane	25 mg daily	25 mg tab 30 tabs	\$224	\$224
	Gefitinib	250 mg daily	250 mg tab 30 tabs	\$1,806	\$1,806
	Imatinib	Maintenance: 600 mg daily	100 mg tab 30 tabs	\$615	(2x100mg plus 400mg) \$3,669
	Imatinib	Starting: 400 mg daily	400 mg tab 30 tabs	\$2,440	\$2,440
	Letrozole	2.5 mg daily	2.5 mg tab 30 tabs	\$224	\$224
J8700	Temozolomide	150-200 mg/m2 daily for 5 days	20 mg cap 5 caps	\$150	Ex: 225 mg dose \$1,677
J8700	Temozolomide	See above	5 mg cap 5 caps	\$39	See above
J8700	Temozolomide	See above	250 mg cap 5 caps	\$1,836	See above
J8700	Temozolomide	See above	100 mg cap 5 caps	\$744	See above
	Thalidomide	200-1200 mg daily	50 mg cap	N/A	Estimates: \$10,000 per
	Thalidomide	Depending on indication	100 mg cap	N/A	Course of treatment
	Thalidomide	See above	200 mg cap	N/A	See above
	Toremifene	I tab daily	60 mg tab 30 tabs	\$114	\$114

^{*}Pricing for these drugs was difficult to obtain as there are no HCPCS found for most of these drugs. Additionally, those drugs with HCPCS codes were assigned "S" codes. "S" codes are Temporary National Codes that are not covered and are not valid for Medicare and would result in non-payment. Consequently, pricing was obtained from web based Canadian and other online pharmacies, and therefore probably reflect lower costs than might be obtained through normal pricing in the United States.

It should be noted that some of the unit pricing for the drugs listed in the above grids might give the impression of a reasonable charge based on dosing for an average person (around 70 kg, with body surface area 1.5 m2). However, number of units given per treatment in addition to frequency of dosages per day over number of days and weeks would have a significant impact on overall costs. SNFs have been charged for 30 and 40 units of a drug with expenses in the \$10,000+ range.

B. Radioisotopes And Their Administration

CMS should exclude the radioisotope drugs provided below in Table 7. 17

Table 7: Listing of Excluded Radioisotopes with corresponding hospital outpatient "C" Codes

HCPCS	Descriptors	Dosage	Pricing	APC Status
C1082, A9522	Supply of radiopharmaceutical diagnostic imaging agent, ibritumomab tiuxetan	per mCi	2,769.63	В
C1083, A9523	Supply of rediopharmaceutical therapeutic imaging agent, yttrium-90 ibritumomab tiuxetan	per mCi	23,976.91	В
C1080, A9533	Supply of radiopharmaceutical diagnostic imaging agent, 1-131 tositumomab		2,565.00	В
C1081, A9534	Supply of radiopharmaceutical therapeutic imaging agent, 1-131 tositumomab	per millicurie	22,230.00	В

It should be noted that a radiopharmaceutical is a radiotherapeutic substance linked to a radioisotope administered to deliver therapeutic radioactivity and combines elements of both chemotherapy and radioisotope categories excluded under BBRA

C. New Drugs Without Specifically Assigned HCPCS For Exclusion

CMS should consider new drugs without specifically assigned HCPCS for exclusion from consolidated billin; i.e., C9399 and J3490 HCPCS, which are codes that represent unclassified drugs, should be excluded from consolidated billing. On May 28, 2004 Transmittal 188, Change Request 3287 reported an amendment to Section 1833(t) of the SSA by adding paragraph (15), Payment of New Drugs and Biologicals Until HCPCS Code Assigned. Under this provision, Medicare now covers payment for an outpatient drug or biological that is furnished by a hospital outpatient department for which a product-specific HCPCS code has not been assigned. Hospital outpatient departments are to use HCPCS C9399, Unclassified drug or biological, which is equivalent to J3490. Consequently, SNFs are being held financially responsible for payment of these newly approved drugs that have not been assigned a specific HCPCS code.

Medicare is paying hospitals for these drugs at 95% of AWP. However, SNFs are being charged much higher amounts for these drugs and do not have specific HCPCS to assist in researching the costs or Medicare allowable amounts. Additionally, hospitals have the opportunity to apply for pass-through status on new drugs. Pass-through status provides hospitals with extra payment for the new drugs, as these drugs are considered to have costs that are significant as compared with payments that would otherwise be made. SNFs do not have this opportunity or advantage. SNFs are still required to pay for these drugs with their PPS rates, which do not take into account these added high costs. In essence, these drugs are unbundled for hospital outpatient departments, but bundled for SNFs. Also, these drugs meet the exclusionary criteria of beyond the scope of SNF care, high cost and low probability.

¹⁷ CMS Manual System, Pub. 100-04, Medicare Claims Processing, Transmittal 360, November 5, 2004, Major Category III, C., Additional Excluded Services Rendered by Certified Providers, Radioisotopes and Their Administration.

D. Additional Recommended Exclusions

1. Magnetic Resonance Imaging (MRI)

CMS should add the following HCPCS code to its exclusions for magnetic resonance imaging (MRI). 18

Table 8:

HCPCS	Descriptor	Pricing*	Comments
76393	Magnetic Resonance Guidance for	562.15	This is a magnetic resonance code that was not
	needle placement		included in the list of exclusions.

^{*} Pricing was obtained from 2005 Physician's Fee Schedule

2. Hyperbaric Oxygen Therapy

CMS should remove the following HCPCS code for hyperbaric oxygen therapy from the list of non-excluded outpatient surgery and related procedures. ¹⁹

Table 9:

HCPCS	Descriptor	Pricing**	Comments
99183	Hyperbaric Oxygen therapy	\$10,000	This procedure meets the criteria of beyond the scope
		-\$40,000	of SNF care, high cost and low probability.

^{*} CMS indicates that inclusions, rather than exclusions, are provide regarding outpatient surgery and related procedures because of the great number of surgery procedures that are excluded and can only be safely performed in a hospital operating room setting.

Hyberbaric Oxygen (HBO) is a medical treatment in which the patient is entirely enclosed in a pressure chamber breathing 100 percent oxygen at greater than one atmosphere pressure. The treatment can cost over \$1,000. HBO does the following:

- increases the concentration of dissolved oxygen in the blood, which enhances perfusion;
- stimulates the formation of a collagen matrix so that new blood vessels may develop;
- replaces inert gas in the bloodstream with oxygen, which is then metabolized by the body; and

^{**} Pricing is based on actual invoices from hospitals for hyperbaric oxygen therapy

¹⁸ This drug should be added to the list of excluded MRI HCPCS codes in CMS Manual System, Pub. 100-04, Medicare Claims Processing, Transmittal 360, November 5, 2004, Major Category III, C., Magnetic Resonance Imaging (MRIs).

CMS should remove the following HCPCS code for hyperbaric oxygen therapy from the list of non-excluded outpatient surgery and related procedures in CMS Manual System, Pub. 100-04, Medicare Claims Processing, Transmittal 360, November 5, 2004, Major Category I, F., Outpatient Surgery and Related Procedurers.

works as a bactericide.

This modality is used primarily to treat decompression illness, carbon monoxide poisoning, and gas gangrene. HBO is also considered acceptable in treating acute vascular compromise and as adjuvant therapy in the management of disorders that are refractory to standard medical and surgical care. The following are the wound care modalities covered:

- Preparation and preservation of compromised skin grafts (not for primary management of
 wounds -- excludes artificial skin graft). Preservation of compromised skin grafts utilizes
 HBO therapy for graft or flap salvage in cases where hypoxia or decreased perfusion has
 compromised viability. HBO therapy enhances flap survival. Should a graft or flap fail,
 HBO therapy may be used to prepare the already-compromised recipient site for a new
 graft of flap. HBO therapy is not covered for the initial preparation of a skin graft site
 and is not considered medically-necessary for the preservation of normal,
 uncompromised skin grafts or flaps;
- Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical
 management. Chronic refractory osteomyelitis is an infection in bone that persists or
 recurs, following appropriate interventions. Such interventions include the use of
 antibiotics, aspiration of abscess, immobilization of the affected extremity, and surgery.
 Medicare Part A can cover the use of HBO for chronic refractory osteomyelitis that has
 been demonstrated to be unresponsive to conventional medical and surgical management;
- Treatment of osteoradionecrosis and soft tissue radionecrosis. HBO is one part of an overall plan of care, along with debridement or resection of nonviable tissues, in conjunction with antibiotic therapy;
- Treatment of soft tissue radionecrosis as an adjunct to conventional treatment; and
- Diabetic wound of the lower extremities in patients who meet the following three indications:
 - Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
 - Patient has a wound classified as Wagner grade III or higher; and
 - Patient has failed an adequate course of standard wound care.

The use of HBO therapy is covered as an adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care.

HBO is generally available in university hospital settings since such hospitals have a tertiary patient population referrals base for this specialized treatment. Residents can be treated in the SNF setting for their wound therapy and receive HBO as adjunctive therapy as indicated above. But HBO therapy, as indicated above, is very expensive, and SNF access for these types of patients is at risk of becoming increasingly difficult.

B. Site of Service Consolidated Billing Rule

CMS should modify the site of service consolidated billing rule. Section 4432(b) of the BBA, the consolidated billing requirement, placed on the SNF the Medicare cost and billing responsibility for virtually all of the services that the SNF's residents in a Part A covered stay receive, except for a small number of services that the statute specifically excludes from this provision. As indicated above, Section 103 of the BBRA amended this provision by further excluding a number of high-cost, low probability services within several broad categories that otherwise remained subject to the provision.

However, CMS itself early recognized that some services that patients could receive while in a SNF Part A stay were outside the scope of SNF services. These were, according to CMS, "intensive diagnostic or invasive procedures that are specific to the hospital setting." 63 Federal Register 26298, May 12, 1998. CMS determined that these services, "under commonly accepted standards of medical practice lie exclusively within the purview of hospitals rather than SNFs, and thus were "not subject to consolidated billing." Id. Over time, under this standard, CMS has excluded magnetic resonance imaging (MRI), computerized tomography (CT) scans, ambulatory surgery involving the use of an operating room, cardiac catherization, hospital outpatient radiation therapy, hospital outpatient angiography, and certain lymphatic and venous procedures. However, in order to be excluded from PPS, the services must be provided in a hospital. If they are provided in a freestanding clinic, such as a radiation therapy clinic, they are not excluded.

We applauded the exceptions when they were provided because of CMS' recognition that such intensive and invasive procedures are not within the purview of the SNF. In 1998, the advent of PPS, CMS was reflecting then current medical practice in its development of the regulatory PPS exclusions. However, medical practice has changed, and the services in question are no longer exclusively within the purview of hospitals. While they remain outside the purview of SNFs, radiation therapy is now commonly provided in freestanding radiation therapy clinics, and MRIs are available from freestanding entities. Our understanding is that freestanding ambulatory surgery clinics have also been growing.

CMS should examine current medical practice and modify its policy of permitting certain services to be excluded only if provided in a hospital and permit these same exclusions if services are provided suitably and appropriately in sites other than hospitals, chiefly freestanding clinics. This policy change should be considered, at a minimum, for ambulatory surgery, MRIs, and radiation therapy services. Such a modification of this policy will not increase costs to the Medicare program -- and indeed may result in cost savings. Simply put, payment will be made to the freestanding clinic instead of the hospital. There is no reason why a hospital monopoly should be retained when services can effectively, efficiently, and safely be provided in an alternative environment.

Further, there is no legal impediment to this policy change. There is no statute requiring that these CMS-provided exclusions must be provided in a hospital. As indicated above, CMS created this policy based on two factors: (1) that these services that patients could receive while in a SNF Part A stay were outside the scope of SNF services, and (2) that at the time of

implementation of the PPS, these were "intensive diagnostic or invasive procedures that [were] specific to the hospital setting." 63 Federal Register 26298, May 12, 1998. Certain of these intensive diagnostic or invasive procedures are no longer specific to the hospital setting because of changes in medical practice and technology. However they remain outside the scope of SNF services. It is well within CMS' regulatory purview to update the policy to include providers, in addition to hospitals, who are now commonly providing these intensive diagnostic and invasive procedures.

Furthermore, and most importantly, a change in policy would enormously facilitate access to care in rural areas -- areas that now are being increasingly served by freestanding clinics. **The benefit to patients in rural areas is clear**. SNFs will not have to transport patients to distant hospitals for provision of excluded services when the services are available from closer freestanding clinics.

VI. Qualifying 3-Day Inpatient Hospital Stay Requirement

AHCA Recommendations on the 3-Day Stay Requirement for SNF Part A Post Acute Care

- CMS should enable SNFs to rely in good faith on a hospital attestation that the 3-day stay requirement has been met. If the attestation later turns out to be incorrect, the beneficiary and the SNF should be held to be without fault and bear no financial responsibility for the Part A SNF stay;
- CMS should include all time spent by a beneficiary in an acute care hospital in the calculation of the 3-day stay requirement;
- CMS should exercise the discretion of the Secretary to eliminate the requirement of qualifying 3-day stay requirement; and
- CMS should, at a minimum, initiate a demonstration to evaluate the implications of selectively eliminating the 3-day inpatient hospital stay requirement.

Discussion

CMS invites comments on the 3-day hospital stay requirement for SNF coverage. Specifically, for beneficiaries whose formal admission to the hospital as an inpatient is immediately preceded by time spent in hospital observation status, CMS has asked whether CMS should count the time spent in observation status towards meeting the SNF benefit's qualifying 3-day hospital stay requirement.

AHCA's position regarding the 3-day stay is threefold: First, CMS should require hospitals to attest that the beneficiary has met the requisite 3-day stay. The beneficiary and the SNF should be able to rely on this attestation and not be held financially responsible if the 3-day stay requirement was not met. Second, all days spent in a hospital prior to the DRG-based stay should count toward the calculation of the 3-day stay. Third, CMS should exercise its authority to eliminate the mandatory requirement of a 3-day hospital stay as a requirement for Part A SNF services. The agency has already done this with regard to the Medicare managed care program wherein Medicare Advantage plans have the discretion to place beneficiaries directly into SNF Part A stays without a prior 3-day stay in a hospital.

A. Hospitals Should Be Required to Certify That The 3-day Stay Requirement Has Been Met

CMS should require hospitals, who are the only entities privy to all the hospital records, to attest to the existence of a bona fide 3-day qualifying stay -- an attestation that the beneficiary and the SNF can rely on in good faith and that only the hospital can provide. If the attestation later turns out to be incorrect, the beneficiary and the SNF should be held to be without fault and not financially responsible for the stay. The attestation could be memorialized via hard copy handed to the SNF as part of the hospital discharge/transfer papers or by posting the attestation on an appropriate HIPAA-compliant CMS web site, established solely for this purpose.

In 2003, the HHS Office of the Inspector General (OIG) issued a series of reports to all FIs calling for recoupment of claims that the OIG believed may have been paid incorrectly due to the potential lack of a 3-day stay. The OIG's review encompassed calendar years 1997 through 2001 and to SNF stays nationwide. AHCA aggressively opposed recoupment on many grounds. On November 26, 2003, CMS, with concurrence from the OIG, informed the FIs that they should not seek to recover the payments identified by OIG in these studies. In addition, CMS stated that if the FIs had already recovered funds as a result of implementing the OIG findings, they were to immediately reverse these transactions and return the payments to the providers.

The OIG reports themselves and AHCA analysis have provided ample evidence of the difficulties involved in the correct determination, administration, and review of the 3-day stay rule. CMS in its directive to the FIs declared that its central office staff were working with OIG to analyze its existing policies, and to make recommendations for future action. We are not aware of any recommendations that CMS has made and continue to believe that the hospital must incur the obligation, and administrative and financial responsibility, for correctly determining the 3-day stay. The difficulties that were raised by the OIG and AHCA which led to the rescission of the recoupment directives must be considered by CMS.

1. It Is Virtually Impossible for CMS to Verify a Qualifying 3-Day Stay

The OIG itself acknowledged that it is "virtually impossible" for CMS to verify that a 3-day stay has occurred. In the reports, the OIG said that it attributed the "significant" amount of improper Medicare SNF payments to the lack of automated procedures within the CMS common working file (CWF) and the FI claims processing systems. It indicated that for many reasons SNF claims cannot be matched against a history file of hospital inpatient claims to verify that a qualifying hospital stay preceded the SNF admission. The OIG concluded that neither the CWF nor the FIs have an automated means of assuring that the SNF claims are in compliance with the 3 consecutive day inpatient hospital stay regulations and eligible for Medicare reimbursement.

The OIG failed to state that the SNF also lacked an automated means of assuring that its claims are in compliance with the 3 consecutive day inpatient hospital stay regulations. Further, the OIG stated that instead of an automated match of inpatient and SNF claims data, SNFs were on an honor system. It failed to state that the hospitals were also on the honor system, but that the choice of the term "honor system" carried with it the clear implication that when something goes wrong in this process, it is a breach of the honor system. AHCA pointed out that this approach, which utterly neglects the inherent difficulties and deficiencies in the 3-day determination process, was misleading, gratuitous, and harmful to providers and their hardworking SNF staff.

The OIG Reports included the following: A-05-02-00087 (UGS) March 2003; A-05-02-00086 (Administar Federal) March 2003; A-05-02-00088 (Palmetto GBA) March 2003; A-05-03-00036 (First Coast Services Options, Inc.) March 2003; A-05-03-00026 (Care First of Maryland, Inc) March 2003; A-05-03-00083 (Mutual of Omaha) March 2003; A-05-03-00015 (Riverbend GBA) April 2003; A-05-03-00022 (Empire HealthChoice) Inc. May 2003; A-05-03-00051 (Cahaba Government Benefit Administrators) July 2003; A-05-03-00035 (Veritus Medicare Services) July 2003; A-05-03-00050 (TriSpan Health Services) September 2003; A-05-03-00086 Arkansas Blue Cross and Blue Shield) October 2003; and A-05-03-00087 (Blue Cross and Blue Shield of Georgia, Inc.) October 2003.

2. The Applicable Rules Complicate the Determination of a Qualifying 3-Day Hospital Stay

At the time of the OIG reports, AHCA could not know, and obviously neither could the OIG, the FIs, nor CMS have known, how many of the alleged ineligible stays would actually turn out to be ineligible. We believed that many of them had the potential of being eligible due to factors such as the interplay of the 3-day rule and the so-called 30-day transfer rule and other complicating and extenuating circumstances. We stated our belief that the OIG should have provided such information in its reports as necessary regulatory background to understanding the nature of the FI databases.

Pursuant to Section 1812(a) of the Social Security Act, a Medicare beneficiary is eligible to receive "post-hospital extended care services" or SNF benefits under Part A for up to 100 days during any spell of illness. Section 1861(i) provides that the term "post-hospital extended care services" means extended care services furnished an individual after transfer from a hospital in which the beneficiary was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer. The beneficiary must have been admitted to the SNF within 30 days after discharge from the hospital, or within such time as it would be medically appropriate to begin an active course of treatment, in the case of an individual whose condition is such that SNF care would not be medically appropriate within 30 days after discharge from a hospital. This rule is referred to as the 30-day transfer rule.

Another aspect of the 30-day transfer rule is provided in the SNF Manual at 212.3(c). The manual provides that if an individual who is receiving covered posthospital extended care leaves a SNF and is readmitted to the same or any other participating SNF for further covered care within 30 days, the 30-day transfer requirement is considered to be met. Thus, the period of extended care services may be interrupted briefly and then resumed, if necessary, without hospitalization preceding the readmission to an SNF. The fact that the period of extended care services could be resumed without hospitalization also means that the period could be resumed with less than a 3-day hospital stay.

The interplay of the 3-day stay and the 30-day transfer rule illustrates how a hospital stay that is less than 3 days may actually be a second hospital stay in a benefit period. This could happen in at least the following two ways:

-

As discussed further below, the 3-day rule is a blunt and crude instrument for controlling the utilization of Medicare Part A skilled nursing services. It has no clinical basis and should be reexamined as a requirement for a SNF Part A stay. The Medicare Catastrophic Coverage Act of 1988 (repealed in 1989) eliminated the 3-day stay in addition to providing other important and beneficial modifications to the Medicare SNF benefit -- unfortunately for a very brief period of time.

Skilled Nursing Facility Manual (CMS-Pub. 12), § 212.3 (A) provides as follows: "In determining the 30-day transfer period, the day of discharge from the hospital is not counted in the 30 days. For example, a patient discharged from a hospital on August I and admitted to an SNF on August 31 was admitted within 30 days. The 30-day period begins to run on the day following actual discharge from the hospital and continues until the individual is admitted to a participating SNF, and requires and receives a covered level of care. Thus, an individual who is admitted to an SNF within 30 days after discharge from a hospital, but does not require a covered level of care until more than 30 days after such discharge, does not meet the 30-day requirement...If an individual whose SNF stay was covered upon admission is thereafter determined not to require a covered level of care for a period of more than 30 days, payment could not be resumed for any extended care services he may subsequently require even though he has remained in the facility. Such services could not be deemed to be "posthospital" extended care services...."

- A beneficiary has a 3-day hospital stay and is admitted to a SNF from the hospital. The beneficiary remains in the SNF for more than 30 days and is discharged to the hospital. She/he has a hospital stay of less than 3 days and is discharged back to the SNF. Within the OIG database, however, the SNF readmission would be erroneously associated with the second hospital stay which was within the 30 days, but less than a 3-day stay.
- A beneficiary has a 3-day hospital stay and is admitted to a SNF within 30 days. The beneficiary is discharged to home care from the SNF with benefits remaining. Within 30 days of the discharge from the SNF, the beneficiary is readmitted to the hospital and stays less than 3 days and is once again admitted to the SNF. The beneficiary would still be eligible to use the remaining SNF benefit on the basis of his/her return to the SNF within 30 days of the previous SNF stay. Again, within the OIG database, the SNF readmission would be erroneously associated with the second hospital stay which was within the 30 days, but less than a 3-day stay.

In addition, CMS permits a lapsed period of more than 30 days for SNF admissions where the patient's condition makes it medically inappropriate to begin an active course of treatment in a SNF within 30 days after hospital discharge. A variety of circumstances and examples pertaining to the exception are provided in the CMS Skilled Nursing Facility Manual (CMS-Pub. 12) Section 212.3. See Attachment 1. It is clear that the overall complexity of the application, and exceptions to the application, of the 3-day and 30-day rules can severely undermine correct and clear determination of the inpatient 3-day stay.

Mutual of Omaha, in its response to the OIG report, also provided additional reasons, alluded to above, as to why there might be inaccuracies in the OIG data. Mutual pointed out that since the auditors did not review medical records, some conclusions and extrapolation might be inaccurate. The FI was of the opinion that further review of the claim history and medical records would be needed to determine if any other factors were contributory, such as the following:

- The qualifying hospital stay occurred at a VA or other non-Medicare facility, for which CWF would have no record.
- The beneficiary may have been in a Medicare+Choice HMO and disenrolled from the HMO before admission to the SNF, in which case CWF would not have a record of the hospital stay.
- A physical disaster situation, such as a hurricane, flood, etc., occurred whereby CMS approved the payment of the SNF stay without a qualifying hospital stay.
- The hospital stay was paid "outside of CWF" in accordance with a special process allowed by CMS to allow payment to be made when there is a system problem.

Obviously it was not known how many of the alleged ineligible claims will prove to be eligible based on the factors discussed above. However, the OIG should have acknowledged and

provided information on these factors and complexities. Its silence on these matters may have contributed to a totally misleading characterization of SNF behavior.

3. The Hospitals Alone Have Control of The Qualifying Information

As the OIG pointed out, there is no automated means for the CWF nor for any FI to assure that the SNF claims are in compliance with the 3-day rule. Even more importantly, there is no automated means for the SNF itself to have such assurance. The SNF must depend on the quality of the (generally faxed) transfer papers arriving with the beneficiary from the hospital, the competence and honesty of the hospital discharge planners (who are also on a so-called honor system), and the mutual comprehension of the hospital and SNF staff of the impact of the 3-day rule in the individual circumstances of each and every discharge from a hospital to a SNF. Unfortunately, given the current system, the opportunities for mistakes are legion. While this was not acknowledged by the OIG in its reports, we believe that this fact greatly influenced the OIG's agreement to withdraw the recoupment directives.

We have heard and continue to hear from providers about the difficulty of dealing with some hospitals and getting from discharge planners indisputably correct information on many issues, including the existence of a *bona fide* 3-day stay.

The first and foremost problem with SNF reliance on the hospital for admission information is the issue of what constitutes a 3-day inpatient stay for the purpose of SNF Part coverage. A transfer form will have the day of hospital admission and the day of hospital discharge. Hospital staff themselves are not particularly focused on the problem of what constitutes an admission day for the purpose of SNF claims because of a lack of an appropriate 3-day stay. Likewise, hospital staff are not always aware that, currently, emergency room and observation stays cannot constitute part of the 3-day span. This is compounded by the fact that Medicare law and other CMS rules pertaining to the hospital itself work to confound the issue by requiring that the costs of services provided to patients during the 3 days immediately preceding the date of the patient DRG admission be considered operating costs of inpatient hospital services and bundled to the DRG stay and payment.²³ As we argue below, a more logical policy would be for CMS to include all days immediately preceding the DRG component in the calculation of the 3-day stay requirement to enable beneficiaries to receive their SNF Part A benefits.

Secondly, dates of admission and discharge on the transfer forms can be wrong, and verification of the dates with hospital staff can be unnecessarily challenging -- and perhaps part of a larger problem regarding the exchange of information between hospital and SNF staff. The primary means of hospitals communicating with nursing facilities regarding a pending placement is via a fax machine. Often, the records sent are abbreviated or unreadable because of poor fax access or print quality. (No one wants to wait for a 50-page fax to go through, so the hospital staff may only send the 15 pages that they think are important.) Indeed, hospital discharge planners generally have little awareness of the need for nursing facilities to collect data for a variety of reasons such as for the Assessment Reference Date (ARD) or "look-back" periods that include hospital stay days.

²³ See Section 1886(a)(4) of the Social Security Act and Medicare Claims Processing Manual, Pub. 100.4, Chapter 3 Inpatient Hospital Billing, Section 40.3 Outpatient Services Treated As Inpatient Services.

Lastly, because of financial pressures, few facilities can afford to send an assessment nurse to the hospital to more adequately determine the condition of each potential resident before admission. Therefore, the facility is left to rely solely upon information from the admitting physician and whatever information the hospital chooses to send. Complicating this situation is the increasing frequency of "last-minute" discharges from hospitals, often on Friday to reduce the weekend staffing pressures on the hospital. If a new resident arrives at a nursing facility late Friday afternoon, nursing facility staff may not be able to reach the hospital's nursing supervisor, discharge planner, or other knowledgeable professional until the following Monday.

In conclusion, many problems, articulated above, can contribute to the inaccurate calculation of the 3-day stay. CMS obviously has to address and resolve all of these problems in an effort to make the 3-day stay a viable and operationally-feasible requirement for a post acute SNF stay. The first step is to CMS should require hospitals, who are the only entities privy to all the hospital records, to attest to the existence of a bona fide 3-day qualifying stay -- an attestation that the SNF can rely on and that only the hospital can provide. If the attestation later turns out to be incorrect, the beneficiary and the SNF should be held to be without fault and bear no financial responsibility for the Part A SNF stay.

B. All Time Spent By A Beneficiary In An Acute Care Hospital Must Be Counted for Purposes of Meeting the 3-day Stay Requirement

As indicated above, CMS invites comments on whether CMS should consider the possibility of counting the time spent in observation status toward meeting the SNF benefit's qualifying 3-day hospital stay requirement. AHCA's position is that all days spent in a hospital prior to the DRG based stay should count toward the calculation of the 3-day stay, and AHCA has long argued this to CMS. In addition, AHCA is part of a coalition of 18 associations and groups who have collectively argued to CMS that beneficiaries' access to care and services continues to be jeopardized by the interpretation of federal law that denies Medicare reimbursement for SNF stays when the beneficiaries have been hospitalized for three or more days.²⁴ The coalition wrote to CMS in 2003 and 2004 that no change in law was needed and that we were seeking modifications only in CMS' Medicare manuals to make them recognize and conform to contemporary medical practice. We wrote that "In light of declining hospital lengths of stay since the Medicare program was first enacted – the average length of stay for older people who were hospitalized declined from 12.6 days in 1970 to 5.8 days in 2001 – these modifications are necessary to assure that Medicare beneficiaries receive the SNF-covered care to which they are entitled."²⁵ This continues to be AHCA's position.

Alliance for Retired Americans, American Association of Homes and Services for the Aging, American College of Health Care Administrators, American Federation of State, County, and Municipal Employees, American Health Care Association, American Medical Directors Association, Catholic Health Association of the United States, Families USA. Morris J. Kaplan, Esq., NHA, Gwynedd Square Nursing Center (Lansdale, PA), Medicare Rights Center, National Academy of Elder Law Attorneys, National Association of Directors of Nursing Administration in Long Term Care, National Association for the Support of Long-Term Care, National Association of Professional Geriatric Care Managers, National Association of Social Workers, National Association of State Long-Term Care Ombudsmen, National Citizens Coalition for Nursing Home Reform, and the National Senior Citizens Law Center.

25 Letters to Laurence D. Wilson from Toby S. Edelman, Center for Medicare Advocacy, Inc, July 3, 2003 and July 15, 2004 on behalf of the above referenced coalition of 18 association and groups.

1. Declining Hospital Length of Stay Threatens Beneficiary Coverage

According to the Medicare Advisory Commission (MedPAC), the average length of hospital stays fell more than 30 percent during the 1990s, with annual declines exceeding 5 percent from 1993 to 1996. The decline has continued through 2003 though slowing to 1.3 percent in 2003. Congress itself had developed concern over declining lengths of stay when, in the BBA, it expanded Medicare's' transfer policy to include discharges to PPS-exempt hospitals and other post-acute settings. According to MedPAC, at the time the Congress was considering this policy, data showed Medicare inpatient length of stay had dropped 22 percent between 1990 and 1995. According to FY 2004 MedPar data, out of the 523 valid DRGs, 61 DRGs (11.7 percent) had geometric mean lengths of stay of less than 2 days, 213 DRGs (40.7 percent) had geometric mean lengths of stay of less than 3 days, and 322 DRGs (61.6 percent) had geometric mean lengths of stay of less than 4 days.

Given the dramatic shift in hospital length of stays, it is imperative that CMS revisit its policy regarding calculation of the 3-day stay. CMS itself acknowledges a key factor -- that at the time Medicare was enacted the concept of observation status itself was not yet even envisioned. CMS admits that it is aware that over time, practice and treatment of observation time may have changed and that thus the effect of not counting this observation time under the existing policy ultimately might be to restrict SNF coverage to a narrower segment of the beneficiary population than the Congress originally intended.

Despite CMS' insight into the negative impact of not counting observation days, the agency suggests that it is noteworthy that Congress has not chosen to amend Section 1861(i) of the Act specifically to reflect use of observation time as triggering the SNF benefit. However, Congress need not legislate changes in policies that are purely creatures of regulation. CMS itself invented the exclusion of observation days and all time spent in the hospital from calculation of the 3-day stay. Congress does not need to act in order CMS to change a policy that is so harmful to the legitimate application of beneficiary Medicare benefits.

2. Medicare Law Permits The Secretary to Include All Time Spent in The Hospital to Be Counted Towards the 3-Day Stay

Indeed, there is no statutory impediment to the change. Under the Social Security Act, post-hospital extended care services are covered by Medicare hospital insurance if the patient is "transferred from a hospital in which [s]he was an inpatient for not less than 3 consecutive days before [her] discharge from the hospital in connection with such transfer." 42 U.S.C. §1395x(i). The Secretary has full authority to interpret the term "inpatient" in a manner that would define the 3-day stay as including all time spent in the hospital but has chosen not to do so.²⁹ CMS

27 Report To The Congress, Medicare Payment Policy, MedPAC, March 2000, page 81.

²⁶ Report To The Congress, Medicare Payment Policy, MedPAC, March 2005, page 46.

²⁸ Notice of Proposed Rulemaking, Hospital Inpatient Prospective Payment System, 70 <u>Federal Register</u> 23306, May 4, 2005, Table 5, at page 23415.

²⁹ See 42 CFR 409.30 and Medicare Benefit Policy Manual, Chapter 8 – Coverage of Extended Care (SNF) Services Under Hospital Insurance, Section 20.1.

itself acknowledges that the policy of not counting all the time spent in a hospital towards the 3-day stay is no more than a "longstanding policy interpretation" of the governing law and does not claim that it is barred from re-interpreting the statute to expand the concept of the 3-day stay.

CMS, however, is obviously bothered by the fact that the Section 1886 requirement discussed above (i.e., that the costs of services provided to patients during the 3 days immediately preceding the date of the patient DRG admission are to be considered operating costs of inpatient hospital services and are bundled to the DRG stay and payment) could be used to support counting these same days as part of the 3-day post-acute requirement.

CMS argues that the deeming requirement in Section 1886(a) and the 3-day requirement for SNF coverage in Section 1861(i) serve different purposes. The deeming requirement in Section 1886(a) was intended to prevent hospitals from "unbundling" services from the inpatient stay and inappropriately seeking separate payment while the purpose of the 3-day inpatient stay requirement for SNF coverage is to target SNF coverage to individuals requiring a short-term, fairly intensive stay in a SNF as a continuation of an acute hospital stay. CMS argues that Congress chose to target SNF coverage to individuals who had been inpatients for at least 3 consecutive days; the Congress could have chosen a shorter time, or it could have specified that certain time before admission must be counted for purposes of the 3-day requirement, but it did not. CMS thus concludes that the requirement in Section 1886(a) of the Act to treat certain preadmission costs as inpatient costs) is consistent with not counting time spent in the hospital prior to an individual's inpatient admission as inpatient time, for purposes of the 3- day requirement for SNF coverage under Section 1861(i) of the Act.

In so arguing, CMS forgets its own acknowledgments that at the time Medicare was enacted the concept of observation status itself was not yet even envisioned, that over time, practice and treatment of observation time may have changed and that thus the effect of not counting this observation time under the existing policy ultimately might be to restrict SNF coverage to a narrower segment of the beneficiary population than the Congress originally intended. Lastly, if the purpose of the 3-day inpatient stay requirement for SNF coverage, as CMS argues, is to target SNF coverage to individuals requiring a short-term, fairly intensive stay in a SNF as a continuation of an acute hospital stay, including all time spent in the hospital towards the 3-day stay in no way abrogates that purpose.

3. Both Emergency Room Time and Observation Days Should Be Included In the 3-Day Stay Requirement

CMS goes to great lengths to distinguish the nature of observation time from time spent in the hospital's emergency room, indicating that it is not willing to consider time spent in an emergency room toward the calculation of the 3-day stay. CMS argues that although both observation services and emergency room services are directed at patients who are expected to spend only a short period of time in that service area, they are in many other ways dissimilar, and CMS details what it considers to be the dissimilarities.

CMS' exercise is irrelevant to the issue, however. The issue is not what constitutes emergency room outpatient services as opposed to observation days. AHCA is not trying to change or expand emergency room or observation services as provided and paid for by Medicare. The

issue is rather that the time spent receiving emergency room services or observation services should count toward the 3-day stay when this time is followed by admission to a DRG stay. The patient is the same patient and the services received as an emergency room outpatient or as an observation stay patient have confirmed the acuity of the patient and the need for acute care which has, in effect, already begun. As indicated by the United States District Court in Elizabeth Jenkel v. Shalala, all such days should be counted, given the likelihood that any patient who is "formally" admitted as an inpatient after an emergency or observation stay has experienced a continuous course of care.

The court held that the 3-day requirement was met by a combination of one night in the emergency room and two days in the hospital after formal admission.³⁰ The court said that "the sequence of events established a continuous course of care that began when the beneficiary was treated in the emergency room and continued until her discharge and transfer to the SNF. Neither the beneficiary's condition nor the course of treatment varied from the time of her arrival at the emergency room to the time of her formal admission. Accordingly, the ALJ erred in reasoning that the beneficiary's hospital stay did not begin until she was formally admitted. The beneficiary's formal admission as an inpatient was merely a ratification of her de facto admission when she arrived at the emergency room. Therefore, the beneficiary satisfied the 3-day prior hospitalization requirement, and the SNF services she subsequently received were covered."31

In conclusion, there is no reason to exclude emergency room services from inclusion in the 3-day stay calculation.

C. The Requirement of a 3-Day Inpatient Hospital Stay Should Be Eliminated or Modified

AHCA strongly recommends that CMS exercise the Secretary's discretion under the Social Security Act and eliminate the requirement for a 3-day hospital inpatient stay.³² We urge CMS to move forward as this is an outmoded and essentially arbitrary precondition for covering a SNF stay under Part A of Medicare. While it is obvious that the treatment of certain conditions/diagnoses require a hospital stay, it is also obvious that there is no rational basis for a universal requirement of a 3-day regardless of diagnosis. Indeed, the Medicare Catastrophic Coverage Act of 1988 repealed the requirement and relied on physician determination of the appropriate site of care.³³ AHCA believes that eliminating the 3-day stay will not increase overall health care spending or Medicare costs.

³⁰ Report and Recommendation of Smith, U.S. Magistrate U.S. District Court, District of Connecticut, No. 2:92-290 (AHN), Dec. 21, 1993, Magistrate's report and recommendation adopted by the court Jan. 26, 1994.

See CCH Paragraph 42,121.

³² Under Section 1812(f) the Secretary may authorize coverage of SNF care without a prior hospital stay if two conditions are met; first, the coverage of these services must not result in any increase in Medicare program payments, and second, the coverage must not alter the acute care nature of the benefit. CMS has determined that these conditions are met in the case of SNF services furnished by a Medicare Advantage plan that covers SNF

³³ The Medicare Catastrophic Coverage Act of 1988 eliminated the 3-day stay in addition to providing other important and beneficial modifications to the Medicare SNF benefit -- unfortunately for a very brief period of time due to the repeal of the Act in 1989.

1. Cost Impact of Eliminating the 3-Day Stay

Eliminating the 3-day stay will increase neither overall health care spending nor Medicare costs. We believe CMS has taken significant steps to recognize the need to change arbitrary rules and recognize the value of the SNF benefit. There are two areas worth noting: the hospital transfer rules and the IRF rules. Over time, Medicare has substantially revised payment policy for inpatient hospital admissions, perhaps most notably with regard to those DRGs most likely to result in transfers to post-acute facilities. The current notice of proposed rulemaking for hospital inpatient payments proposes a significant expansion in the "transfer DRG" policy, increasing the number of DRGs subject to reduced payment for short-stays that result in post acute care from the current 29 DRGs to 231 DRGs.

In 2003, there were .9 million discharges from the 29 hospital "transfer DRGs" to SNFs. If the 231 proposed hospital "transfer DRGs" had been in effect in 2003, the number of hospital transfer DRG discharges to SNFs would have increased by .7 million, to a total of 1.6 million. CMS should consider waiving the 3-day stay requirement where such a transfer is necessary but may be before there is a 3-day stay qualifying event.

Medicare payment rates for SNFs are substantially lower than payment rates for IRFs or LTCHs. In a recent report (*Medicare: More Specific Criteria needed to Classify Inpatient Rehabilitation Facilities,* April 2005), the Government Accountability Office (GAO) found that "Medicare pays for treatment in an IRF at a higher rate than it pays for treatment in other settings."

For 2006, projected average payments per admission for IRFs and LTCHs range from over 1.5 to over 3.5 times higher than SNF costs. Unlike discharges from hospital to SNFs, neither IRFs nor LTCHs are subject to the 3 day stay requirement. In 2003, using the 29 DRG hospital "transfer DRG" policy, there were .25 million discharges to IRFs. According to the GAO report, many of the IRF discharges could have been treated at lower cost – resulting in savings to Medicare – by being admitted to SNFs rather than IRFs (or LTCHs).

The asymmetrical requirement -- whereby Medicare covered admissions to the more expensive IRFs and LTCHs are not subject to the arbitrary and outmoded 3-day hospital stay requirement, but Medicare covered admissions to SNFs are subject to the 3-day stay rule – distorts incentives and interferes with the most appropriate and cost-effective placement of Medicare beneficiaries who need post-acute care. Therefore CMS should consider SNF as an appropriate location fro the admission of patients who are otherwise admitted to a LTCH or IRF with out a 3-day stay requirement.

2. If CMS Fails to Eliminate the 3-Day Stay Requirement, It Should at a Minimum Initiate a Demonstration To Evaluate the Implications of Selectively Eliminating the Requirement

AHCA hopes to end this long-standing stalemate, where highly significant changes in medical treatment and payment policy dramatically change site-of-care and length of stay apparently have no effect on an arbitrary rule instituted 40 years ago. We believe this stalemate is caused by CMS concerns about cost, an incomplete understanding of the gains for Medicare beneficiaries that would result from modifying the 3-day stay requirement, and an absence of

objective data. Thus, at a minimum, CMS should initiate a demonstration to evaluate the implications of selectively eliminating the 3-day inpatient hospital stay requirement.

In conjunction with the new proposed hospital transfer DRG policy, AHCA proposes that CMS test on a nationwide basis, for a time-limited period, eliminating the 3-day stay requirement only for those DRGs subject to the transfer payment policy. CMS should conduct a rigorous evaluation of the effects of this demonstration. Based on the results of the demonstration, be reinstituted if CMS determines that net federal spending – including Medicaid spending on long term care – increased as a result of the demonstration. If the Secretary determines that the demonstration was not budget neutral, the 3-day stay requirement could be reinstituted but the Secretary could nevertheless determine that the gains in patient quality and satisfaction were sufficient to justify further consideration of selective elimination of the 3-day stay. If the results of the evaluation were to show that the demonstration was budget neutral for the federal government, he Secretary would could extend the elimination of the requirement beyond the transfer DRGs.

VII. Pay for Performance

AHCA Recommendations on the Development of a Pay-for-Performance System:

- CMS should work in conjunction with the long term care profession in its development of any pay-for-performance methodology in order to ensure that the system best measures quality outcomes for long term care patients and residents and facilitates further quality improvements;
- CMS should develop a pay-for-performance program that is flexible enough to allow for changes in the customer's expectation of quality as well as changes in quality outcomes brought about by technology and advances in medicine.
- CMS needs to evaluate and make public the impact on pay-for-performance from changes brought about by the use of MDS 3.0 prior to program adoption and implementation.

Discussion

AHCA recognizes that designing a pay-for-performance system for SNFs involves many complex issues, most critical are reliable and sufficient funding and the capability to measure performance. Since the ability to determine funding requirements is contingent on current and projected performance, the issue of valid and reliable quality measures is paramount.

The major challenge in performance measurement for SNFs is the lack of a valid and reliable set of measures from which to holistically assess SNF quality performance. Currently the two primary sources of SNFs performance are compliance with the federal survey criteria and the measures that comprise the National Nursing Home Quality Initiative. Both programs have merit within their respective domains, and have universal participation. Unfortunately neither was designed to be a sole source for assessing quality performance and each has been challenged by well documented problems of accuracy. Additionally these two measurement programs are not aligned or integrated with each other and rely on different data collection tools which further reduce the potential of merging their capabilities.

Currently, there is no central definition of quality care, how should it best be measured in the SNF setting and what incentives ought to be implemented to further the quality improvements the profession has produced. AHCA believes that the lack of national consensus on a definition of quality is and continues to be a barrier to achieving quality outcomes. For this reason, we have developed a definition of quality, publicly offered in comments to CMS and others and have published it in the August 2004 issue of *Provider* in an article titled "Defining Quality In Long Term Care." This definition combines the key elements of two other definitions of quality. Both the American National Standards Institute (ANSI) and the American Society for Quality (ASQ) define quality as the totality of features and characteristics of a product or service that bears on its ability to satisfy given needs. We combined aspects of this definition

with one of the most popular definitions developed by James Evans and James Dean, Jr. ³⁴ According to Evans and Dean, to beat the competition, organizations often must "exceed customer expectations."

Our proposed definition of quality - "the totality of service features and characteristics that meet or exceed customer needs and expectations" - recognizes that no single process outcome or segment of outcomes will provide quality. It is the totality of the features and characteristics that must be considered before quality or poor quality is proclaimed. A facility having a low pressure ulcer prevalence rate does not provide quality if other clinical practices are poor or their adherence to regulation is determined inadequate. Or, a facility with good clinical and survey results does not assure a quality operation if their delivery of care and services is done without respect for the patient's preferences and dignity.

The value of a congruent definition of what constitutes quality in long term care cannot be underestimated. Such a definition provides the "means" test to determine the family of measures which represent quality in long term care. These measures will have meaning for consumers and providers, and for directing the appropriate funding of performance-based rewards.

In July of 2002 the long term care profession launched the Quality First Initiative. The success of this initiative, which embodies the profession's pledge to quality to the American public, will be assessed by six outcomes which include:

- There will be continued improvement in compliance with federal regulations.
- There will be demonstrable progress in promoting financial integrity and preventing occurrences of fraud.
- There will be demonstrable progress in the quality of clinical outcomes and prevention of confirmed abuse and neglect.
- There will be measurable improvements in all Centers for Medicare & Medicaid Services Continuous Quality Improvement measures.
- High rates on consumer satisfaction surveys will indicate improved consumer satisfaction with services.
- There will be demonstrable improvement in employee retention and turnover rates.

These outcomes are inclusive of the current performance measurement criteria in the survey process, the NHQI measures, include special emphasis on abuse and neglect (a key concern for consumer groups, recognize the importance of financial integrity, and champion the value of customer satisfaction and staff stability). We recognize that simply grouping these measures does not go far enough but it forms the conceptual basis on which to build a more rigorous set of measures.

Last year AHCA began an extensive internal policy making process to develop a pay-for-performance policy that would best serve the entire spectrum of AHCA member facilities. We determined that a pay-for-performance program should be a vehicle that encourages quality and rewards providers based on improving care and exceeding certain benchmarks. In constructing

³⁴ Total Quality: Management, Organization, and Strategy, 3rd ed., (Mason, Ohio: South-Western, 2003). p. 9-10.

a pay-for-performance program based on this concept, the best way to measure quality needs to be considered and incorporated in the program. We believe the following guidelines address the pay-for-performance considerations that are the most relevant to nursing homes. They also provide the basis legislation drafted by AHCA for introduction in Congress.

- Measures should include a mix of structure, process and outcome measures.
- Measures need to be evidence-based and developed with a purpose statement and a statement on unintentional consequences associated with linking payment to performance.
- Measures need to be under the control of the facility.
- Measures need to be risk adjusted when appropriate and validated.
- Quality measures and standards must be developed by CMS in conjunction with the industry.
- The pay-for-performance program needs to include a provision that all measures will be continually updated and evaluated for validity and relevancy.
- The application of pay-for-performance for SNFs should be phased-in over a reasonable time period to allow under-performing facilities to improve their quality before penalization begins.
- The initial incentives for participation should start at a lower percentage and increase over time in order to accommodate the impact of the phase-in and to assure compliance with budget constraints.
- SNF pay for performance methodology and measures should first be tested prior to full implementation and testing must be representative of all types and sizes of facilities in all states.
- The payment rates established should in no case be less than the RUGS rates for FY 2005, including the 6.7 percent and 20 percent add-ons, as adjusted annually by the market basket.

We believe that CMS can play a leadership role that will bring together all the stakeholders and design a system that will help define the standards that should be used to measure quality and create continuous quality improvements in long term care. AHCA offers our definition of quality as a starting point for discussion. Our hope is that this will provide the impetus for the other payers to adopt the same or similar measures and lead to a singular unified system of measuring quality. We look forward to working with CMS on the design of a pay-for-performance system.

VIII. Development of An Integrated Approach To Payment and Delivery of Post-Acute Services

AHCA Recommendations On The Development of An Integrated Post-Acute Payment and Delivery System:

- CMS should complete the mandated report to Congress due January 1, 2006, on the development of instruments to assess the health and functional status of beneficiaries using post-acute care and other specified services. CMS should involve nursing facility experts on patient assessment as instrument(s) are finalized, tested and revised and actively involve AHCA in the development of an integrated post-acute payment and delivery system;
- CMS should work on developing an integrated post-acute payment system that is based on a uniform patient assessment instrument for post-acute care settings and ensures that financial incentives result in the best clinical post-acute placement for the patient;
- In the interim, CMS should make changes within the existing systems that would better align financial incentives with clinical placement decisions. These include tightening and enforcing new and existing certification criteria for IRFs and LTCHs, and enhancing the role of the QIOs in reviewing appropriateness of patient placement;
- CMS should use hospital discharge planning as a starting point to standardize post-acute assessment tools. For patients with prior hospital stays, CMS should continue to apply hospital discharge planning that is already required by law and regulations;
- As CMS develops health information technology for use by nursing homes, CMS should include nursing homes in the developmental process and provide opportunities throughout the developmental process for nursing homes to offer its input and expertise;
- CMS should assist nursing facilities to upgrade and improve their information technology infrastructure by providing funding and technical assistance; and
- CMS should evaluate the need for continued MDS 3.0 development and validation given the CMS goal of creating a uniform assessment tool.

Discussion

In its discussion of post-acute payment systems, CMS indicates that due to the independent development of each payment system, the agency focused on phases of a patient's illness as defined by a specific site of service, rather than on the entirety of the post-acute episode from the standpoint of the patient. CMS expresses the need to investigate a more coordinated approach to payment and delivery of post-acute services that focuses on the overall post-acute which could entail providing payments to ensure that beneficiaries receive high quality care in the most appropriate setting, so that admissions and any transfers between settings occur only when consistent with good care, rather than to generate additional revenues.

In order to accomplish this objective, CMS acknowledges the necessity of collecting and comparing clinical data across different sites of service. CMS agrees with the Medicare Payment Advisory Commission (MedPAC) and other stakeholders that it should look at a full range of options in analyzing post-acute care payment methods. Lastly, it encourages incremental change and emphasizes the importance of automated tools that will effectuate communication and comparison of clinical data across different sites of care. CMS invites comment on these polices and administrate actions that could provide maximum support for further steps towards higher quality care.

A. Appropriate Placement for Beneficiaries Needing Post-Acute Care

AHCA supports Medicare payment and delivery system adjustments that ensure the most appropriate placement for Medicare beneficiaries needing post-acute care. Such system improvements may include implementing a uniform patient assessment instrument for post-acute care settings and ensuring that financial incentives result in the best clinical post-acute placement for patient. All improvements must be patient-centric, i.e., based solidly on patient characteristics and outcomes, and be based on a common patient-centered quality assessment system.

Currently, the Medicare program pays separate, prospectively-set rates to providers in four different post-acute care settings: skilled nursing facilities (SNFs), long-term acute care hospitals (LTCHs), home health agencies (HHAs), and inpatient rehabilitation facilities (IRFs). We observe many distinctions among these provider types. CMS requires different patient assessment instruments for three of the four post-acute care provider categories. The law requires that each provider type be certified under separate criteria. CMS ensures patient safety and quality in each of these settings through vastly different regulatory structures. In addition, the physical settings in which patients receive care greatly differ, ranging from a patient's home to a nursing home to a hospital.

Most post-acute care providers, physicians and others involved in patient care believe in a hierarchy of acuity among the different settings and assume that patients with the highest acuity clinical needs will receive care in the highest acuity setting. Some research as well as provider experience shows that different post-acute care settings sometimes serve similar patients. This overlap in patient populations can occur for legitimate non-clinical reasons or clinical reasons that are not measurable by research; however, the overlap is sometimes inappropriate and results in Medicare overpayment.

For certain patient diagnoses, IRF payments can be up to three times more than SNF payments, and LTCH reimbursements can be up to ten times more. Some of this is clearly due to variations in severity of illness, but because there are no common patient assessment tools or outcomes measures across all settings, it is not possible to ascertain whether patients are being treated in the most appropriate setting and whether resources are being allocated efficiently and appropriately.

CMS, Congress and MedPAC are concerned about the ambiguity of patient placement within the current post-acute care system. As a result, all have recently discussed the study and eventual

design of a unified Medicare post-acute care payment system. At the March 2005 MedPAC meeting, members discussed problems stemming from the current multiple post-acute systems such as overlap in services and lack of criteria delineating the appropriate treatment setting and the sensitivity of post-acute decisions to payment system incentives. On June 16, 2005, the U.S. House of Representatives Ways and Means Health Subcommittee also held a hearing on this topic.

At the hearing, Mary Ousley, Immediate Past President of AHCA, made clear our support of the concept. Ms. Ousley stated that:

First and foremost, it is essential for CMS to develop a patient centered core uniform screening and assessment tool for post acute care, and a uniform integrated payment system based on this comprehensive assessment tool. But until CMS can finalize and apply a uniform system, it can do a better job of placing post acute patients in the most appropriate care settings. For example, AHCA supports the use of hospital discharge planning as a starting point to standardize post acute assessment tools.

The director of the Center for Medicare Management at CMS also told the Committee that "it is time to consider ways of improving coordination of payment and clinical assessment across care settings to provide a more seamless system of post-acute care services." Specifically, Director Herb Kuhn stated, "ultimately, we should focus our efforts on developing a system that provides payment and assures quality for the overall post-acute care episode, rather than each individual component of the continuum of care." In theory, such a system would pay all post-acute providers the same rate regardless of the setting where care is provided. This payment would then vary by clinical factors such as patient diagnosis, severity of illness, and resources necessary to treat patients.

As part of this effort, AHCA urges CMS to develop a common patient-centered quality assessment system as a part of any post-acute healthcare delivery structure. This quality assessment system would provide consumers with consistent, comparable data necessary to enable them to make informed decisions regarding the most appropriate placement of family and loved ones based on patient quality outcomes across post-acute settings. As we discuss later, technology, such as advanced hospital discharge planning tools, has and can continue to make a huge contribution to consumer decision regarding the appropriateness of care placement.

B. Critical Factors In The Development of An Integrated Post-Acute Payment System

1. Assessment Tool

AHCA applauds CMS' comprehensive assessment tool plans announced at the June 16, 2005 Ways and Means hearing. At the hearing, CMS staff stated that the agency will begin testing by the spring of 2006 a patient assessment tool for all post-acute care services under Medicare as a first step toward the possible creation of an integrated post-acute care payment system for the industry. AHCA urges CMS, in the creation of this tool, to develop it with a structure that supports Consolidated Health Informatics (CHI) standards to foster electronic data transmission and interoperability across care settings.

AHCA encourages CMS to make every effort to meet the Spring 2006 timeframe for testing a patient-centered uniform screening and assessment tool for post-acute care. To aid in this process, CMS should complete the report to Congress due January 1, 2006 on the development of instruments to assess the health and functional status of beneficiaries using post-acute care and other specified services. CMS is required to make recommendations on the use of patient assessment instruments for payment purposes. The assessment instrument required by BIPA is to have readily comparable, statistically compatible, common data elements. The standard instruments developed are to supersede the assessment tools now required.

CMS must develop an assessment tool that is robust, reliable, comprehensive and interoperable across all settings and for all populations. The development of such a tool is a very complicated and important task. CMS should ensure active participation by clinicians most familiar with each post-acute care setting in order to incorporate the full range of clinical information necessary to appropriately assess patients across the spectrum of post-acute care providers.

The assessment tool should capture important social factors that affect the type of setting most appropriate for the individual. For example, a SNF may be more appropriate than home health for the sole reason that family support is inadequate to maintain a person at home. Given recent research that shows the significant stress (anxiety and depression) related to institutionalization of a significant other, ³⁶ the role of and proximity to family is an important consideration in the placement assessment process.

As important as family considerations are consumer preferences, which an assessment focused exclusively on clinical needs would miss. Even in a market where all types of post-acute care providers are available, a consumer may have a strong preference for a particular provider because of social, financial, or other reasons.

Lastly, CMS should CMS should evaluate the need for continued MDS 3.0 development and validation given the CMS goal of creating a uniform assessment tool and involve SNF experts on patient assessment as the tool is finalized, tested, and revised.

2. The Importance of Improved Information Technology

AHCA applauds CMS' conclusion that improved information technology is critical for the post-acute and long term care systems and strongly agrees that today and in the future there should be requirements for information exchange among long term care settings (i.e., SNFs and other post-acute care settings, assisted living settings, home health care, and independent living settings) acute care and ambulatory care settings that would support a unified post-acute care PPS. This is especially true as care evolves from a static incident reporting health system to a dynamic disease management system where complete resident patient health and trends are taken into

³⁵ The Benefits Improvement and Protection Act of 2000, Section 545.

³⁶ Long-term Care Placement of Dementia Patients and Caregiver Health and Well-being, *Journal of the American Medical Association*, August 25, 2004, Vol. 292, pgs. 961-967.

consideration during the process of care planning. As CMS states, such an information flow would be critical to the success of a comprehensive assessment tool that would span post-acute care settings.

CMS should bring to bear AHCA's expertise and knowledge as the agency advances such initiatives. AHCA has wide array of information technology initiatives that could inform the development of the assessment tool noted above and the related unified post-acute care PPS. For example, we would like to bring CMS' attention to Total Living Choices (TLC), a hospital discharge planning tool that successfully generates timely data to support continuity across hospitals and SNFs. AHCA partners with Total Living Choices in order to provide better communications of hospital based patients' care needs to post acute and long-term care settings. The hospital transmission provides the long term care setting the ability to accept the right patient in the right setting and the ability to schedule the admission date and time. In addition, families and adult children are empowered by using the TLC web tools at the hospital or at home to educate themselves on types of care available, payment options, finding a facility in a desired zip code and ensuring the patient/resident's quality of life and quality of care needs are met.

Another example is the participation of AHCA in the development of the Continuity of Care Record (CCR). The CCR is a standard electronic health record summary developed and accepted through the joint sponsorship of ASTM International (one of the largest standards development organizations and originally the American Society for Testing and Materials), the Massachusetts Medical Society (MMS), the Health Information Management Systems Society (HIMSS), the American Academy of Family Physicians (AAFP). Other sponsors of the CCR, in addition to AHCA, include the American Academy of Pediatrics (AAP), the American Medical Association (AMA), and the National Association of Supportive Service for Long Term Care (NASL).

The CCR is a developing electronic medial record summary standard that contains the most pertinent patient information related to the last completed patient/provider encounter. The genesis of the development of the CCR is from a pre-Minimum Data Set (MDS) discharge summary that hospitals in Massachusetts used when discharging patients to nursing homes, rehabilitation centers and to visiting nursing agencies. The CCR record is designed to electronically follow the patient to the next treating provider or referral facility. The patient will also receive a copy of his/her CCR at the completion of each medical appointment/encounter as appropriate or at the end of an inpatient stay.

The use of the CCR in nursing homes will reduce assessment and documentation burden as CCR data elements similar to the MDS can, at some future point in time, automatically populate the MDS and/or other patient assessment tools. The CCR will provide clinicians the needed patient information to focus clinical assessment and for timely care planning on patient admission to the nursing home. The CCR is key to improving information sharing during transitions of care.

3. Necessary Steps for CMS In Developing Improved Information Technology

In response to its request for comment on administrative actions that could provide maximum support for further steps towards higher quality care, AHCA provides here a series of

actions/steps that CMS must take as it strives to compare clinical data and promote continuity of care across settings.

CMS should participate fully and advocate for the full participation of long term care in the national health information network process to ensure that nursing facilities are part of the information network environment as it becomes standardized.

In addition, as CMS develops automated record tools for use by nursing homes, CMS must include nursing homes in the developmental process and provide opportunities throughout the developmental process for nursing homes to offer its input and expertise. CMS' recently developed Nursing Home Improvement and Feedback Tool (NHIFT), an electronic tool for capturing process data on high-risk pressure ulcers, depression, restraints and pain, provides an example of why it is so important that the CMS developmental process include nursing facilities. NHIFT is a CD-ROM based tool that CMS plans to make available for free to all interested nursing facilities.

However, many nursing homes have web-based systems and cannot use CD-ROMs. Had CMS simply talked with nursing homes as it developed NHIFT, CMS would have understood that due to security and protection constraints, many nursing facilities have eliminated the ability to utilize CD ROM drives and that their software is run from a centralized, fire-wall protected location. As CMS develops automated record tools, it must consider interoperability. To develop tools, such as NHIFT described above or Setting Targets --Achieving Results (STAR), which is designed to assist nursing facilities to set targets related to quality measures, without considering interoperability only continues the fractured system that currently exists.

Further, as CMS establishes an information collection process to satisfy both clinical and payment needs, it should ensure that safeguards are put in place so that both needs are equally addressed. Too often, payment needs become the focus of information collection to the detriment of the quality of information relating to clinical aspects. Lastly, CMS should assist nursing facilities to upgrade and improve their information technology infrastructure by providing funding and technical assistance.

C. Additional Considerations In Structuring An Integrated Post-Acute Payment System

AHCA agrees with the premise that post-acute placement decisions should rely heavily on patient clinical characteristics and needs (as well as social factors mentioned above). Patients who can be safely and effectively cared for in SNFs should not be treated in LTCHS or IRFs. Conversely, severely ill, medically complex patients requiring more intensive therapies should have access to the setting providing them with the most appropriate care, which may or may not be a SNF. However, from a clinical perspective, determinations about appropriate placement are not always clear. In cases where the issues are complex, input from treating physicians is critical. Any system should allow for flexibility so that clinical judgment can be effectively exercised in the best interests of patients.

In addition, CMS should also focus on ensuring that post-acute care providers have the capacity to meet the needs of the patients. Staffing levels, staff skill mix, availability of diagnostic tests,

sophistication of technology and intensity of services vary tremendously across settings. If the goal of a new system is to better match patients with post-acute care settings, it must ensure that the capacity of each provider type is, in fact, the best match for the patients requiring long term care services.

Lastly, adjustments to the post-acute care payment system must not assume that all Medicare beneficiaries have equal access to all types of post-acute care. Even though a beneficiary's clinical profile is a good match to receive home health care, a home health agency may not be available or may not have capacity to take a new patient. Therefore, the system must be flexible enough to allow for limitations in post-acute care supply.

C. Improvement To The Existing Systems

As we stated above, CMS should work towards ensuring that the financial incentives in the Medicare payment system result in the best clinical post-acute placement for patients. However, we also encourage CMS to consider and assess the widest range of policy options available for achieving this goal. There are many potential changes CMS could make within the existing systems that would better align financial incentives with clinical placement decisions.

These include ideas such as tightening and enforcing new and existing certification criteria for IRFs and LTCHs, and enhancing the role of the Quality Improvement Organizations (QIOs) in reviewing appropriateness of patient placement. In addition, as indicated in AHCA's testimony at the Ways and Means hearing on June 16, 2005, AHCA supports the use of hospital discharge planning as a starting point to standardize post-acute assessment tools. For patients with prior hospital stays, CMS should continue to apply hospital discharge planning that is already required by law and regulations.

D. Input and Support

In making adjustments to the post-acute care payment and delivery system, CMS will need support and technical expertise from a wide array of post-acute care stakeholders, including nursing home providers. AHCA represents over 10,000 long term care facilities and has over 140 associate business partner organizations which include experts in patient assessment and the use of information technology in post-acute care and long term care systems. With such national cross-cutting membership base and in-house expertise, AHCA should be actively involved in the process as CMS develops any integrated post-acute payment and delivery system.